

# EXHIBIT B

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF WEST VIRGINIA  
3 AT CHARLESTON  
4  
5 IN RE: ETHICON, INC., PELVIC )  
REPAIR SYSTEM PRODUCTS LIABILITY ) Master File No.  
6 LITIGATION ) 2:12-MD-02327  
 ) MDL 2327  
7 )  
MARABETH CLARK, )  
8 )  
Plaintiff, ) JOSEPH R. GOODWIN  
9 ) U.S. DISTRICT JUDGE  
v. )  
10 )  
ETHICON, INC., et al., ) Case No.  
11 ) 2:12-CV-09251  
Defendants. )  
12 )  
13  
14

15 VIDEO DEPOSITION OF EDWARD STANFORD, M.D.  
16 August 10, 2017, at 11:11 a.m.  
17

18 Reported by: ANNETTE M. DERUYTER, CSR  
Calif. CSR #9816  
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Edward Stanford, M.D.

<p style="text-align: right;">Page 2</p> <p>1 DEPOSITION OF EDWARD STANFORD, produced, sworn,  2 and examined on August 10, 2017, at Doctors Medical  3 Center, 1441 Florida Avenue, in the city of Modesto,  4 state of California, before Annette M. DeRuyter, a  5 Certified Shorthand Reporter.  6  7  8 APPEARANCES OF COUNSEL  9  10 Appearing telephonically on Behalf of Plaintiff:  Wagstaff &amp; Cartmell, LLP  11 4740 Grand Avenue, Suite 300  Kansas City, MO 64112  12 (816) 701-7473  By: Robert G. Groves, Esquire  13 rgroves@wcllp.com  14 On Behalf of Defendants:  Friday, Eldredge &amp; Clark  15 400 West Capitol Avenue, Suite 2000  Little Rock, AR 72201  16 (501) 370-1429  By: Kimberly D. Young, Esquire  17 kyoung@fridayfirm.com  18  ALSO PRESENT:  19 NICHOLAS BOULE, Videographer  20  21  22  23  24  25</p>	<p style="text-align: right;">Page 4</p> <p>1 INDEX OF EXHIBITS  2 DEFENDANT'S DESCRIPTION PAGE  3 Exhibit 1 Stress Urinary Incontinence  Journals 23  4  5 Exhibit 2 Surgeon's Resource Monograph 30  6  7 Exhibit 3 AUGS Practice Bulletin 32  8  9 Exhibit 4 AUGS Position Statement on  Mesh Midurethral Slings for  10 Stress Urinary Incontinence 33  11  12 Exhibit 5 Potential Risks of Non-Mesh  SUI Surgery 39  13 Exhibit 6 Potential Risks of Non-Mesh  and Mesh SUI Surgeries 40  14  15 Exhibit 7 Clinic records 48  16  17 Exhibit 8 TVT Tension-free Vaginal Tape 97  18  19 Exhibit 9 St. Mary's Good Samaritan  Inpatient Registration Form 114  20 Exhibit 10 Curriculum Vitae Edward J.  Stanford, MD, MHA, MS, FACOG,  21 FACS 123  22  23 ---oOo---  24  25</p>
<p style="text-align: right;">Page 3</p> <p>1 INDEX OF EXAMINATION  2 EXAMINATION BY: PAGE  3 Ms. Young 6, 113  4 Mr. Groves 63  5  6 ---oOo---  7  8  9  10  11  12  13  14  15  16  17  18  19  20  21  22  23  24  25</p>	<p style="text-align: right;">Page 5</p> <p>1 Thursday, August 10, 2017  2  3 ---oOo---  4  5 VIDEOGRAPHER: We are now on the record.  6 My name is Nicholas Boule. I am a  7 videographer for Golkow Technologies. Today is  8 8/10/17, and the time is 11:11 a.m.  9 This video deposition is being held in  10 Modesto, California, in the matter of Clark versus  11 Ethicon, et al., for the Southern District of  12 West Virginia.  13 The deponent is Dr. Edwards Stanford.  14 Would Counsel please identify yourselves.  15 MS. YOUNG: Kimberly Young on behalf of  16 Ethicon and Johnson &amp; Johnson.  17 MR. GROVES: Robert Groves on behalf of  18 plaintiff Marabeth Clark.  19 VIDEOGRAPHER: The court reporter is Annette  20 DeRuyter, and will now swear in the witness.  21  22 EDWARD STANFORD, M.D.,  23 a witness herein, having been duly and regularly sworn  24 by the Certified Shorthand Reporter, was deposed and  25 testified as follows:</p>

<p style="text-align: right;">Page 6</p> <p>1</p> <p>2</p> <p>3 EXAMINATION</p> <p>4</p> <p>5 BY MS. YOUNG:</p> <p>6 Q. Good morning, Doctor. Will you please state</p> <p>7 your full name for the record?</p> <p>8 A. Edward Stanford.</p> <p>9 Q. And we met just a few minutes ago before we</p> <p>10 started, but, again, my name is Kim Young, and I am</p> <p>11 here today on behalf of Johnson &amp; Johnson and</p> <p>12 Ethicon.</p> <p>13 A. Okay.</p> <p>14 Q. And we're taking your deposition today</p> <p>15 because you were a treating physician of Ms. Marabeth</p> <p>16 Clark, who has filed a lawsuit that we're here in</p> <p>17 regard to today.</p> <p>18 You and I have never met before today; is</p> <p>19 that right?</p> <p>20 A. Correct.</p> <p>21 Q. And you treated Ms. Clark back in the early</p> <p>22 2000's, and I'm sure you see many patients. Do you</p> <p>23 have any independent memory of her?</p> <p>24 A. No, I do not.</p> <p>25 Q. Have you spoken with any attorney</p>	<p style="text-align: right;">Page 8</p> <p>1 to a residency?</p> <p>2 A. I did. I did a one-year internship in</p> <p>3 general surgery at Cedars-Sinai. That was 1985</p> <p>4 through '86.</p> <p>5 Then I went on to do family medicine at the</p> <p>6 Northridge Medical Center, which is the UCLA Hospital,</p> <p>7 and finished that in 1989 and received my board</p> <p>8 certification to family medicine.</p> <p>9 And then practiced for just about a year in</p> <p>10 Wisconsin. And then went back for training in</p> <p>11 obstetrics and gynecology at Illinois Masonic from</p> <p>12 1990 to 1993. And completed my boards in OB/GYN in</p> <p>13 1996.</p> <p>14 Q. And does this mean you are board certified in</p> <p>15 family medicine and also obstetrics and gynecology?</p> <p>16 A. I let the family medicine boards lapse, and</p> <p>17 I've maintained my boards in OB/GYN.</p> <p>18 Q. Are you a member of any professional</p> <p>19 societies?</p> <p>20 A. The Society of Gynecologic Surgeons, I'm a</p> <p>21 member. I've been a member of many, many societies.</p> <p>22 But right now the society of Gynecologic Surgeons</p> <p>23 and -- oh, and the International Continence Society.</p> <p>24 Q. What is the International Continence</p> <p>25 Society?</p>
<p style="text-align: right;">Page 7</p> <p>1 representing Ms. Clark before your deposition today?</p> <p>2 A. I have not.</p> <p>3 Q. Did you happen to bring an exhibit with -- a</p> <p>4 CV with you today?</p> <p>5 A. No.</p> <p>6 Q. Okay.</p> <p>7 A. Was I supposed to?</p> <p>8 Q. Well, it's fine if you didn't. We're going</p> <p>9 to ask you some questions about your training and</p> <p>10 education and experience. But I'm sure that you'll be</p> <p>11 able to tell us that off the top of your head.</p> <p>12 If you would, Doctor, please tell the ladies</p> <p>13 and gentlemen of the jury where you went to college</p> <p>14 and medical school and the years you graduated.</p> <p>15 A. I went to Pepperdine University and graduated</p> <p>16 in 1979. Then I went to UCLA for graduate school, and</p> <p>17 I completed that in 1983 during medical school. And I</p> <p>18 graduated from med school from the Medical College of</p> <p>19 Pennsylvania in 1985, which is now Drexel University.</p> <p>20 I guess there's been purchases, so I'm an alumni of a</p> <p>21 school I didn't graduate from.</p> <p>22 Q. And what was your graduate degree in at</p> <p>23 UCLA?</p> <p>24 A. Kinesiology or physiology of exercise.</p> <p>25 Q. After completing medical school did you go on</p>	<p style="text-align: right;">Page 9</p> <p>1 A. It's an international society of -- dedicated</p> <p>2 to the science of pelvic floor dysfunction and</p> <p>3 incontinence. It's urologists and urogynecologists, as</p> <p>4 well as physiotherapists and nurses.</p> <p>5 Q. Do you know how long you've been a member of</p> <p>6 that society? Approximately.</p> <p>7 A. A long time. I don't remember. I've been a</p> <p>8 member of either American Urogyn Society, and sat on</p> <p>9 their board of directors. I'm sorry, their executive</p> <p>10 committee.</p> <p>11 American Association of Gynecologic</p> <p>12 Laparoscopists. Sat on their board of directors.</p> <p>13 International Urogyn Association, sat on</p> <p>14 several committees.</p> <p>15 ICS, International Continence Society. Was</p> <p>16 chairman of a couple of committees, including the</p> <p>17 ethics committee.</p> <p>18 American College of OB/GYN, and taught coding</p> <p>19 courses for them for a couple decades.</p> <p>20 SGS, Society of Gynecologic Surgeons. I</p> <p>21 was -- it's by invitation only, and I became a member</p> <p>22 in 2004.</p> <p>23 So a lot of societies. Usually in a</p> <p>24 leadership role.</p> <p>25 MS. YOUNG: Rob, would you mind just muting</p>

<p style="text-align: right;">Page 10</p> <p>1 on your end whenever you're not speaking? I can hear 2 the clicking of the keys. 3 MR. GROVES: Sorry about that. 4 MS. YOUNG: That's fine. I just don't want 5 it to interfere with the video. Thank you. 6 Q. So, Doctor, it sounds as though you've had a 7 particular interest in female urological problems for 8 sometime in your practice; is that fair? 9 A. That's fair. That's true. 10 Q. And when would you say that that particular 11 interest in your practice began? 12 A. In my chief year, my last year of OB/GYN 13 training, I was given the opportunity by my division 14 chief to branch out. Since I'd already finished a 15 surgical internship, another residency, during my last 16 year I was allowed to sort of focus on pelvic 17 reconstructive and laparoscopic surgery. 18 And back then urogynecology was sort of a new 19 field, so there weren't hard- -- there were maybe 20 two fellowships available at that point. So I 21 went this route instead of trying to find a fellowship 22 since there was very few at that point. And since, of 23 course, the field has blossomed and several more 24 fellowships have come into existence. 25 Q. Would that have been in 1996, that final</p>	<p style="text-align: right;">Page 12</p> <p>1 I would say grand rounds or the similar type 2 of thing, well over 100. 3 Q. And for the benefit of the jury, what are 4 grand rounds? 5 A. A hospital educational program, residency 6 academic center might ask for a specialist to come in 7 and talk about a subject matter. And then they 8 present to a department, as well as maybe nursing and 9 residency staff, and usually that's considered a Grand 10 Rounds. It's getting everybody together for -- to 11 listen to a scholarly presentation. 12 Q. How long have you treated patients for stress 13 urinary incontinence? 14 A. Since probably my -- you mean surgical 15 treatment or just treatment? 16 Q. Just treatment in general. 17 A. Oh. My entire medical career. 18 As a family physician I would treat 19 overactive bladder and retentive patients. And then 20 as an OB/GYN I learned about surgical treatment. And, 21 you know, the combination probably since 1987. 22 Q. And when did you begin surgical treatments of 23 your patients for stress urinary incontinence? 24 A. As a resident I would assist on those types 25 of surgeries. And then as a private physician it</p>
<p style="text-align: right;">Page 11</p> <p>1 year? 2 A. Yeah. Yes, it would. 3 Q. Did you publish any articles on treatment of 4 female urologic problems? 5 A. Yes. Probably 30. 6 Q. Have you done any presentations on female 7 urologic problems? 8 A. Yes. 9 Q. Can you estimate how many? 10 A. All over the world. 500. 11 Q. How long have you -- 12 MR. GROVES: Was that 500? 13 THE WITNESS: Yes. 14 MR. GROVES: Thank you. 15 MS. YOUNG: Q. And what types of 16 circumstances have you given presentations under? 17 A. Grand rounds, society meetings, abstract 18 presentations, paper presentations, staff CME 19 presentations. 20 At one point when I was helping some 21 companies with research, I would give lectures, 22 several dozen a year for -- you know, to educate 23 physicians. 24 So, you know, it could be 300. I don't know. 25 I don't know how many I've done.</p>	<p style="text-align: right;">Page 13</p> <p>1 became a focus of my practice for a couple of 2 decades. 3 (Whereupon a conversation 4 was held off the record.) 5 MS. YOUNG: Q. Doctor, what is your current 6 job? 7 A. I am the market chief medical officer for the 8 central California hospital, Tenant hospitals. 9 So Tenant is an AD hospital system. And they 10 have I think 22 or 24 CMOs. And I'm the CMO of the 11 three tenant facilities in Central California. 12 I also don't have the official title of chief 13 operating officer but I have operational oversight 14 over nine clinical departments of this hospital, 15 Doctors Medical Center. 16 Q. With all of those responsibilities, are you 17 still able to see patients at this point in your 18 career? 19 A. I don't operate anymore. I only see patients 20 in the family medicine residence clinic. So I do a 21 gynecologic clinic two or three Fridays a month and an 22 OB clinic two or three Wednesdays a month, and I teach 23 residents. But I don't deliver babies or do surgery 24 for the last two years now. I've gone to the 25 administrative side.</p>

<p style="text-align: right;">Page 14</p> <p>1 Q. I understand.</p> <p>2 So is two years ago the last time that you</p> <p>3 would have performed any surgeries to treat stress</p> <p>4 urinary incontinence?</p> <p>5 A. It would have been June of 2015. That's a</p> <p>6 little over two years.</p> <p>7 Q. And at that time what percentage of your</p> <p>8 practice would involve treatment of stress urinary</p> <p>9 incontinence?</p> <p>10 A. At that point I had curtailed that activity</p> <p>11 because I was the chief of OB/GYN and chief medical</p> <p>12 officer of another hospital. And so it would have</p> <p>13 been about 50 percent of my practice. And the rest</p> <p>14 would have been obstetrics since I was overseeing the</p> <p>15 obstetric division.</p> <p>16 Q. And how many years would you say that the</p> <p>17 treatment of patients for SUI represented about 50</p> <p>18 percent of your practice?</p> <p>19 A. Oh, just those two or three years. The rest</p> <p>20 of it, it was probably 75 to 80 percent. I always did</p> <p>21 a little obstetrics on the side, always.</p> <p>22 Q. But it had been 75 to 80 percent from the</p> <p>23 time that you completed your residency in '96 in that</p> <p>24 field?</p> <p>25 A. Yes. But there was about a -- probably a</p>	<p style="text-align: right;">Page 16</p> <p>1 the practice away from non-mesh procedures. But not</p> <p>2 entirely. There was still a role for mesh</p> <p>3 procedures -- I mean non-mesh procedures.</p> <p>4 Q. When you say you were not a big fan of the</p> <p>5 needle suspension procedures, what were your concerns</p> <p>6 with that procedure?</p> <p>7 A. Historically they had about a 50 percent</p> <p>8 failure rate over time.</p> <p>9 So if the counseling was such that the</p> <p>10 patient would probably be a suitable candidate or had</p> <p>11 health risks that a larger surgery may not be the best</p> <p>12 choice, then a minimally invasive procedure such as a</p> <p>13 staming needle procedure might be done. And it would</p> <p>14 be the patient's choice.</p> <p>15 Q. And when you refer to a needle suspension</p> <p>16 procedure as less invasive, are you saying that it was</p> <p>17 less invasive than a Burch procedure?</p> <p>18 A. Yes.</p> <p>19 Q. Describe if you would for the jury what a</p> <p>20 Burch procedure entails?</p> <p>21 A. A traditional Burch procedure would be an</p> <p>22 incision in the suprapubic region. You would dissect</p> <p>23 between the pubic bone and the bladder. And then you</p> <p>24 would place sutures adjacent to the lower bladder and</p> <p>25 upper urethra and suspend it to a ligament.</p>
<p style="text-align: right;">Page 15</p> <p>1 seven- or eight-year period where I didn't do</p> <p>2 obstetrics at all and I only did gynecology.</p> <p>3 Q. And does gynecology include treatment of</p> <p>4 stress urinary incontinency?</p> <p>5 A. Yes.</p> <p>6 Q. Okay.</p> <p>7 When you were training, were you trained on</p> <p>8 any non-mesh surgical options to treat stress urinary</p> <p>9 incontinence?</p> <p>10 A. Yes.</p> <p>11 Q. And if you would, tell me what those were.</p> <p>12 A. The -- back when I was training, the sort of</p> <p>13 the state of the art at that point was to do a Burch</p> <p>14 procedure. I've done hundreds of open Burch as well</p> <p>15 as laparoscopic Burch procedures.</p> <p>16 Less common would be pubovaginal sling</p> <p>17 procedures. But I've done those in the United States</p> <p>18 as well as in Africa.</p> <p>19 And needle suspensions. I was never a big</p> <p>20 fan of needle suspensions, but I did perform those,</p> <p>21 since they were minimally invasive, on hundreds of</p> <p>22 other patients. And that would have been in the '90s</p> <p>23 up to the early 2000s.</p> <p>24 And then, of course, the minimally invasive</p> <p>25 mesh slings became more prevalent, and so that shifted</p>	<p style="text-align: right;">Page 17</p> <p>1 Now, that could also be done</p> <p>2 laparoscopically. But, again, you have to get into</p> <p>3 the retropubic space. And usually two sutures were</p> <p>4 replaced on each side and suspended with a one hand in</p> <p>5 the vagina lifting and one hand suturing adjacent to</p> <p>6 the lower bladder, upper urethra, and then securing it</p> <p>7 to a ligament and tying it to the point where the</p> <p>8 ureterovesical junction is elevated to stop the urine</p> <p>9 flow. Or urine leakage. Not urine flow, but urine</p> <p>10 leakage.</p> <p>11 Q. And what is it about the mesh slings when</p> <p>12 they came onto the market that made them a preferable</p> <p>13 option in certain cases over the Burch procedure?</p> <p>14 MR. GROVES: Object to form.</p> <p>15 THE WITNESS: Answer anyway?</p> <p>16 MS. YOUNG: Q. You can, yes.</p> <p>17 A. Okay. Great.</p> <p>18 Q. From time to time either one of us might make</p> <p>19 objections.</p> <p>20 A. Sure.</p> <p>21 Q. But they're strictly for the record. But you</p> <p>22 can go ahead and answer.</p> <p>23 A. I guess I didn't quite understand the</p> <p>24 question.</p> <p>25 Q. Sure. And thank you for telling me that. If</p>

<p style="text-align: right;">Page 18</p> <p>1 that ever happens, let me know --</p> <p>2 A. Okay.</p> <p>3 Q. -- and I'll rephrase it.</p> <p>4 I thought that you mentioned that at a</p> <p>5 certain time the -- there were mesh slings that came</p> <p>6 on the market.</p> <p>7 A. Yes.</p> <p>8 Q. And that there was a shift in the procedures</p> <p>9 that you did from more invasive procedures to mesh</p> <p>10 sling procedures. Did I understand that correctly?</p> <p>11 A. Yes.</p> <p>12 MR. GROVES: Object to form.</p> <p>13 MS. YOUNG: Q. Okay.</p> <p>14 A. There was a natural history, yeah. After</p> <p>15 Olmsted's research back in I think '94 maybe, I forget</p> <p>16 the date, there was an interest in mesh sling</p> <p>17 procedures, in particular the TVT procedure. And over</p> <p>18 time as the research developed, it was considered a</p> <p>19 less invasive and highly effective procedure. So more</p> <p>20 of those slings started to be done by folks like</p> <p>21 myself who were treating incontinence.</p> <p>22 Q. When did you first use a mesh product to</p> <p>23 surgically treat stress urinary incontinence?</p> <p>24 A. I don't recall.</p> <p>25 Q. Approximately.</p>	<p style="text-align: right;">Page 20</p> <p>1 did you reach a point where you were comfortable using</p> <p>2 the TVT?</p> <p>3 A. I was actually always comfortable with the</p> <p>4 procedure, but I needed to be able to counsel my</p> <p>5 patient. So I became comfortable that I could give</p> <p>6 the patients some data so they could make a choice.</p> <p>7 Q. I understand.</p> <p>8 Can you estimate the number of patients that</p> <p>9 you surgically treated for SUI before Ms. Clark's</p> <p>10 procedure in 2003, including in that number both mesh</p> <p>11 and non-mesh procedures?</p> <p>12 A. No.</p> <p>13 Q. Just adding up the numbers that you were</p> <p>14 assigning to different types of procedures, was it</p> <p>15 fair to say it was in the hundreds?</p> <p>16 A. Yes.</p> <p>17 Q. Could it have been in the thousands?</p> <p>18 A. Oh, over the course of my career, yes.</p> <p>19 Between '94 and '95 and 2003 is it?</p> <p>20 Q. Yes.</p> <p>21 A. It's in the hundreds.</p> <p>22 Q. Okay.</p> <p>23 And before your procedure with Ms. Clark in</p> <p>24 June of 2003, can you estimate how many TVT procedures</p> <p>25 you would have done by then?</p>
<p style="text-align: right;">Page 19</p> <p>1 A. I actually went and trained with Olmsted in</p> <p>2 Sweden, but I don't recall the first one I did.</p> <p>3 Q. And that is Dr. Olmsted?</p> <p>4 A. Olmsted. He's the one that invented the TVT.</p> <p>5 I believe I have his name correct.</p> <p>6 Q. No, yes, you're correct.</p> <p>7 A. Yes. It's been a long time.</p> <p>8 Q. It has been by this point.</p> <p>9 Do you remember approximately how long you</p> <p>10 trained with him?</p> <p>11 A. Yes. It was about a five-day trip to Sweden.</p> <p>12 And I performed a few cases there and observed several</p> <p>13 cases.</p> <p>14 And then I didn't adopt it right away when I</p> <p>15 came back. So I would say probably '95. Around '95 I</p> <p>16 started incorporating them into my practice.</p> <p>17 Q. And what, if anything, explained the delay in</p> <p>18 when you first came back and when you incorporated it</p> <p>19 into your practice?</p> <p>20 A. I've always been a little bit of a stickler</p> <p>21 for numbers, so I wanted to see more research</p> <p>22 developed.</p> <p>23 Q. And did you see that research?</p> <p>24 A. Yes. It started to come out. Yeah.</p> <p>25 Q. And when the additional research came out,</p>	<p style="text-align: right;">Page 21</p> <p>1 A. I'm not even sure how to arrive at the</p> <p>2 number. Several hundred.</p> <p>3 Q. And we may have covered this a little bit</p> <p>4 earlier, but why did you start using the TVT</p> <p>5 midurethral sling to treat patients with SUI as</p> <p>6 opposed to other surgical options that you had?</p> <p>7 A. Well, again, I was comfortable with the</p> <p>8 procedure. I was comfortable with the preliminary</p> <p>9 research. And then as I became more familiar with the</p> <p>10 procedure, I saw -- personally saw very good success.</p> <p>11 It was less invasive than a Burch, either laparoscopic</p> <p>12 or open Burch. Less time in the hospital. And the</p> <p>13 complication rates were relatively low.</p> <p>14 Q. Did you continue to use the TVT product after</p> <p>15 Ms. Clark's procedure in June of 2003?</p> <p>16 A. Yeah, I have used TVT my entire career. Now,</p> <p>17 you know that, probably after 2005 or '06 when the</p> <p>18 transobturator approach became more popular, the TVT</p> <p>19 use dropped off. And I certainly did convert to the</p> <p>20 transobturator approach, o-b-t-u-r-a-t-o-r.</p> <p>21 So, yes, it was a natural progression of</p> <p>22 newer techniques that I adopted.</p> <p>23 Q. And were you using the TVT with the obturator</p> <p>24 approach at the time that you stopped performing these</p> <p>25 types of surgeries?</p>



<p style="text-align: right;">Page 22</p> <p>1 A. Oh, you mean when I sort of went into my 2 administrative retirement? 3 Q. Exactly. 4 A. Yes, I was doing TVTs and TOTs. 5 Q. Doctor, in an effort to provide quality 6 medical care to your patients, is it fair to say that 7 you've familiarized yourself with safety information 8 before using a new surgical product for the first 9 time? 10 A. Yes. 11 Q. And is that what you touched on earlier when 12 you were talking about training and obtaining data to 13 be able to inform your patients? 14 A. Yes. 15 Q. Is reading medical journals one of the ways 16 you educate yourself about surgeries and medical 17 devices? 18 A. Yes. 19 Q. You also attend medical conferences? 20 A. Less now. But, yes. 21 I usually attended a couple international or 22 U.S. conferences every year. And, of course, there 23 research is presented at all of them. A lot of the 24 research I kind of knew beforehand because I review 25 for journals. At one point I was reviewing for I</p>	<p style="text-align: right;">Page 24</p> <p>1 I was on theirs as well. 2 Q. Do you recall the years that you were on 3 those boards approximately? 4 A. Different times. I don't recall. 5 Q. That's fine. 6 And you also mentioned being a reviewer for 7 journals. Are any of the journals that you served in 8 that role listed here on this list? 9 A. I've actually reviewed for every one of them 10 except the Cochrane Library. 11 Q. Okay. Thank you, Doctor. 12 A. Oh, no, I take that back. I don't think I 13 reviewed for New England Journal. I don't recall 14 doing that. 15 Q. Okay. 16 A. But all the rest, yes. 17 Q. Thank you. 18 As part of educating yourself about different 19 procedures and the efficacy and safety of procedures, 20 do you sometimes confer with medical colleagues on 21 those issues? 22 A. Or they conferred with me, yes. 23 Q. And do you also I'm sure take into account 24 your own clinical experience? 25 A. Yes.</p>
<p style="text-align: right;">Page 23</p> <p>1 think 13 different journals and was on the editorial 2 board of two. And -- or three. 3 And so I would have the opportunity to review 4 a lot of research ahead of time. So I was pretty 5 familiar with data. 6 Q. I am going to hand you what's been marked as 7 Exhibit 1 to your deposition. 8 (Whereupon Defendant's 9 Exhibit 1 was marked for 10 identification.) 11 MS. YOUNG: Q. And it's titled, "Stress 12 Urinary Incontinence Journals." 13 If you would take a look at this list and 14 tell me whether you're familiar with these journals. 15 A. I didn't realize the Cochrane Library 16 (Cochrane Reviews) was a journal, but I'm familiar 17 with all of these. 18 Q. Okay. 19 You mentioned being on the editorial board of 20 two or three journals. Which journals were those? 21 A. The International Urogyn Journal. I was on 22 their editorial board. 23 Female Pelvic Medicine Reconstructive 24 Surgery, I was on their editorial board. 25 The Journal of Minimally Invasive Gynecology,</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. In your opinion is there any surgery that is 2 totally risk free? 3 A. No. 4 Q. In your opinion are there known basic risks 5 to all pelvic floor surgeries? 6 A. Yes. 7 Q. Do you ever guarantee an outcome to a 8 patient? 9 A. No. 10 Q. Anytime that you do a surgery on a woman in 11 her pelvic area, do you discuss with the patients 12 risks associated with that procedure? 13 A. Yes. 14 Q. And would some of those risks associated with 15 the pelvic procedure include pain with intercourse 16 after the procedure? 17 A. Yes. 18 Q. Would they -- the risk also include -- 19 MR. GROVES: Object to form. 20 MS. YOUNG: Q. Would the risk also include 21 vaginal scaring? 22 MR. GROVES: Object to form. 23 THE WITNESS: Yes. 24 MS. YOUNG: Q. Would the risk also include 25 urinary problems such as retention or trouble emptying</p>



<p style="text-align: right;">Page 26</p> <p>1 the bladder?</p> <p>2 A. Yes.</p> <p>3 MR. GROVES: Object to form.</p> <p>4 MS. YOUNG: Q. Were those risks that you</p> <p>5 knew were associated with any pelvic surgery when you</p> <p>6 operated on Ms. Clark?</p> <p>7 MR. GROVES: Object to form.</p> <p>8 THE WITNESS: That would have been a usual</p> <p>9 conversation. What I said to her specifically, I</p> <p>10 don't recall.</p> <p>11 MS. YOUNG: Q. Were those risks that you</p> <p>12 yourself would have been aware of at the time of</p> <p>13 Ms. Clark's procedure in 2003?</p> <p>14 A. Yes.</p> <p>15 Q. If a patient develops a particular side</p> <p>16 effect or complication, does that mean that you have</p> <p>17 made an incorrect choice in recommending the</p> <p>18 surgery?</p> <p>19 MR. GROVES: Object to form.</p> <p>20 THE WITNESS: Not usually, no.</p> <p>21 MS. YOUNG: Q. If a patient develops a side</p> <p>22 effect or complication, does that mean that you made</p> <p>23 the wrong choice in recommending a product to be used</p> <p>24 in surgery?</p> <p>25 MR. GROVES: Object to form.</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Okay.</p> <p>2 Did you have sales reps from many different</p> <p>3 pharmaceuticals companies and medical device companies</p> <p>4 that would call on you or your clinic for their</p> <p>5 products?</p> <p>6 A. They would call, but I wasn't a fan of</p> <p>7 entertaining sales reps.</p> <p>8 Q. That's fair enough.</p> <p>9 Do you recall whether Ethicon sales</p> <p>10 representatives ever left, from time to time, any</p> <p>11 written documents at various times?</p> <p>12 A. Oh, they always drop by and left written</p> <p>13 documents. I couldn't tell you what they were. They</p> <p>14 didn't get read very often.</p> <p>15 Q. Okay.</p> <p>16 Do you know whether or not in the time frame</p> <p>17 of June 2003 there would have been a place in your</p> <p>18 office with brochures available for patients that</p> <p>19 discussed various gynecological issues?</p> <p>20 MR. GROVES: Object to form.</p> <p>21 THE WITNESS: Yeah, it was a bit of an</p> <p>22 expense for the office, but I would purchase ACOG</p> <p>23 bulletins, and I put them up in a rack in the -- in</p> <p>24 one of my offices, I think, it was in the waiting room,</p> <p>25 and the other one it was in a patient access</p>
<p style="text-align: right;">Page 27</p> <p>1 THE WITNESS: I don't believe so.</p> <p>2 MS. YOUNG: Q. If a patient develops a side</p> <p>3 effect or complication, in your opinion does that mean</p> <p>4 that something was wrong with the product you used?</p> <p>5 A. I would -- well --</p> <p>6 MR. GROVES: Object to form.</p> <p>7 THE WITNESS: Yeah, I'm not sure exactly how</p> <p>8 to answer that.</p> <p>9 But, no, I would -- I would answer that if I</p> <p>10 felt it was safe and effective and the patient</p> <p>11 understood the risks, then I would feel comfortable</p> <p>12 proceeding with the procedure. I'm not sure I could</p> <p>13 blame the product, per se, for a known complication.</p> <p>14 Did that answer your question?</p> <p>15 MS. YOUNG: Q. It did. Thank you, Doctor.</p> <p>16 A. Okay.</p> <p>17 Q. When you're deciding whether or not to offer</p> <p>18 a surgery to a patient, do you have to weigh the</p> <p>19 potential risks and side effects with the potential</p> <p>20 benefits?</p> <p>21 A. Every time.</p> <p>22 Q. Do you remember any of the Ethicon sales</p> <p>23 representatives from the 2001 to 2003 period?</p> <p>24 A. I do not. I usually did not interact much</p> <p>25 with the representatives.</p>	<p style="text-align: right;">Page 29</p> <p>1 hallway.</p> <p>2 MS. YOUNG: Q. Can you tell the jury please</p> <p>3 what ACOG stands for?</p> <p>4 A. American College of Obstetrics and</p> <p>5 Gynecology.</p> <p>6 Q. Do you recall whether you ever used a</p> <p>7 brochure relating to the TVT sling?</p> <p>8 A. I don't recall.</p> <p>9 Q. Do you recall whether you would have given</p> <p>10 Ms. Clark any Ethicon brochure related to the TVT</p> <p>11 sling?</p> <p>12 A. I don't recall.</p> <p>13 Now, that said, usually there was a -- there</p> <p>14 would have been some sort of description of what the</p> <p>15 procedure looks like. And I don't recall back then</p> <p>16 what educational materials I might have used. But I'm</p> <p>17 not a great artist, so I probably had a photograph or</p> <p>18 a picture or a pelvic model, and I would show them.</p> <p>19 I do know that I had the trocars in the</p> <p>20 office at one point to demonstrate what the procedure</p> <p>21 meant. And when I would use the word trocar, most</p> <p>22 patients wouldn't know what that meant, so I would</p> <p>23 show them.</p> <p>24 Q. And can you explain for the jury what a</p> <p>25 trocar is?</p>

<p style="text-align: right;">Page 30</p> <p>1 A. Yeah.</p> <p>2 The mesh product is delivered under the pubic</p> <p>3 bone with the help of a metal stick that's shaped in a</p> <p>4 way that would introduce a track for the device to be</p> <p>5 implanted. And then -- so that was a trocar. A</p> <p>6 metal -- a curved metal implant stick, for lack of a</p> <p>7 better word.</p> <p>8 Q. And when you say you would use a model, is</p> <p>9 that a model of the anatomy that would be involved in</p> <p>10 the procedure?</p> <p>11 A. Yes. I had some pelvic models in the office</p> <p>12 that I would use to demonstrate different types of</p> <p>13 surgeries to different patients.</p> <p>14 Q. Do you know the source of any of the</p> <p>15 photographs or illustrations you may have used to</p> <p>16 describe a procedure to your patient?</p> <p>17 A. I really don't recall what I used then.</p> <p>18 Sorry. I don't recall.</p> <p>19 Q. That's all right.</p> <p>20 I'm going to hand you what's been marked as</p> <p>21 Exhibit 2 to your deposition. It's titled, "Surgeon's</p> <p>22 Resource Monograph."</p> <p>23 (Whereupon Defendant's</p> <p>24 Exhibit 2 was marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 32</p> <p>1 bulletins issued by the American College of Obstetrics</p> <p>2 and Gynecologists?</p> <p>3 A. Yes.</p> <p>4 (Whereupon a conversation</p> <p>5 was held off the record).</p> <p>6 MS. YOUNG: I'm going to hand you what's been</p> <p>7 marked as Exhibit 13. I'm sorry, as Exhibit 3.</p> <p>8 (Whereupon Defendant's</p> <p>9 Exhibit 3 was marked for</p> <p>10 identification.)</p> <p>11 MS. YOUNG: Q. If you would, would you read</p> <p>12 the title of that practice bulletin?</p> <p>13 A. Urinary Incontinence in Women.</p> <p>14 Q. And do you recall whether or not you received</p> <p>15 that practice bulletin?</p> <p>16 A. From November 2015, I don't recall.</p> <p>17 Well, first of all, I would not have received</p> <p>18 it. I would have to go and look for it myself.</p> <p>19 Q. Okay.</p> <p>20 A. And I'm not -- I don't recall having read it</p> <p>21 either.</p> <p>22 MR. GROVES: Is that an ACOG bulletin?</p> <p>23 MS. YOUNG: Yes, it was.</p> <p>24 Q. Okay. Now I'm going to hand you what has</p> <p>25 been marked as Exhibit 4 to your deposition.</p>
<p style="text-align: right;">Page 31</p> <p>1 MS. YOUNG: Q. Is this something that you</p> <p>2 recall ever receiving a copy of during your training</p> <p>3 on the TVT midurethral sling?</p> <p>4 MR. GROVES: May I ask, is Exhibit 2 dated?</p> <p>5 THE WITNESS: Yes.</p> <p>6 MS. YOUNG: It is. It says on the front page</p> <p>7 a report of June 2000 Summit Meeting.</p> <p>8 MR. GROVES: June 2000 Summit Meeting?</p> <p>9 MS. YOUNG: Yes.</p> <p>10 MR. GROVES: Thank you.</p> <p>11 MS. YOUNG: You're welcome.</p> <p>12 THE WITNESS: I don't recall this monograph.</p> <p>13 But I recall the -- these black and white pictures on</p> <p>14 page five, I believe it is --</p> <p>15 MS. YOUNG: Q. Okay.</p> <p>16 A. -- I do recall these pictures.</p> <p>17 And I'm pretty sure I had something similar</p> <p>18 to this in the office to demonstrate what the</p> <p>19 procedure was.</p> <p>20 I don't recall this monograph though.</p> <p>21 Q. Is it possible you received the monograph but</p> <p>22 don't remember as you sit here today whether you</p> <p>23 remember it?</p> <p>24 A. Sure, it's possible, yes.</p> <p>25 Q. Do you from time to time review practice</p>	<p style="text-align: right;">Page 33</p> <p>1 (Whereupon Defendant's</p> <p>2 Exhibit 4 was marked for</p> <p>3 identification.)</p> <p>4 MS. YOUNG: Q. A physician's statement</p> <p>5 issued by AUGS. It's an acronym, A-U-G-S.</p> <p>6 Here you go, Doctor.</p> <p>7 A. Give me just one second. I'm looking at</p> <p>8 this.</p> <p>9 Q. Sure.</p> <p>10 MR. GROVES: What's the date of this, the</p> <p>11 AUGS statement?</p> <p>12 MS. YOUNG: Yes, I was just about to get to</p> <p>13 that. January 2014.</p> <p>14 Q. Doctor, could you read the title of that</p> <p>15 position statement, please?</p> <p>16 A. Position statement on Mesh Midurethral</p> <p>17 Slings for Stress Urinary Incontinence.</p> <p>18 Q. And what is the organization that issued the</p> <p>19 physician's statement?</p> <p>20 A. The American Urogynecologic Society, in</p> <p>21 conjunction with the Society of Urodynamics, Female</p> <p>22 Pelvic Medicine and Urogenital Reconstruction. SUFU,</p> <p>23 S-U-F-U.</p> <p>24 Q. Thank you.</p> <p>25 Doctor, I'm going to read you some statements</p>

<p style="text-align: right;">Page 34</p> <p>1 from this and then ask you whether or not you agree 2 with them. All right? 3 A. Yes. 4 Q. "The polypropylene mesh midurethral sling is 5 the recognized worldwide standard of care for the 6 surgical treatment of stress urinary incontinence." 7 MR. GROVES: Object to form. Also object to 8 this use of this exhibit. Lacking in foundation. 9 MS. YOUNG: Q. "The polypropylene mesh 10 midurethral sling is the recognized worldwide standard 11 of care for the surgical treatment of stress urinary 12 incontinence. The procedure is safe, effective, and 13 has improved the quality of life for millions of 14 women." 15 MR. GROVES: Object to form. Object to this 16 use of this exhibit. Lacking in foundation. 17 MS. YOUNG: Q. Doctor, do you have the 18 January 2014 physician's statement in front of you? 19 A. I do. 20 Q. And if you will look at the very first page, 21 there's an introductory paragraph that's italicized, 22 which is the source of the statement I just read. 23 Do you agree with that statement today? 24 MR. GROVES: Again, object to form. Lack of 25 foundation.</p>	<p style="text-align: right;">Page 36</p> <p>1 MS. YOUNG: That's all right. If you feel 2 more comfortable with that, we'll do it this way. 3 THE WITNESS: Yeah, I don't take it 4 personally, okay. 5 MR. GROVES: I'm sorry. I'm just this guy 6 joining by phone. You guys are traveling and taking 7 time out of your day, so I just want to be as polite 8 as I can. Sorry about that. 9 MS. YOUNG: That's quite all right. 10 Q. The next statement is, "The monofilament 11 polypropylene mesh midurethral sling is the most 12 extensively studied anti-incontinence procedure in 13 history." 14 Do you agree with that statement today? 15 MR. GROVES: Object to form. Lack of 16 foundation. 17 THE WITNESS: That's probably true. 18 MS. YOUNG: Q. Did you agree with that 19 statement at the time of Ms. Clark's implant in June 20 of 2003? 21 MR. GROVES: Object to form. Calls for 22 speculation. Lack of foundation. 23 THE WITNESS: I'm not sure. 24 MS. YOUNG: Q. That's okay. 25 Is that because of the time that's lapsed</p>
<p style="text-align: right;">Page 35</p> <p>1 THE WITNESS: Well, it's a rather broad 2 statement, but I think it's accurate. 3 MS. YOUNG: Q. And the next statement I'm 4 going to read is "Polypropylene material is safe and 5 effective as a surgical implant." 6 Do you agree with that statement today? 7 A. I do. 8 MR. GROVES: Object to form. Lack of 9 foundation. 10 MS. YOUNG: Q. Did you agree with the two 11 statements I just read at the time of Ms. Clark's 12 implant in June of 2003? 13 A. Yes. 14 MR. GROVES: Object to form. Lack of 15 foundation. 16 THE WITNESS: Still yes. 17 MS. YOUNG: Counsel, would you like a 18 continuing objection to any questions from this 19 position statement? 20 MR. GROVES: I'll just keep objecting to form 21 and lacks foundation on this particular exhibit. I'm 22 not quite sure if I'm entitled to a continuing 23 objection under the rules. 24 I apologize, Counsel. And to you, Doctor. 25 I'm sorry if I'm talking over you as well.</p>	<p style="text-align: right;">Page 37</p> <p>1 between now and then? 2 A. Yes. 3 Q. Poly -- the next statement is, "Polypropylene 4 mesh midurethral slings are the standard of care for 5 the surgical treatment of SUI and represent a great 6 advance in the treatment of this condition for our 7 patients." 8 Do you agree this statement today? 9 MR. GROVES: Object to form. Lack of 10 foundation. 11 THE WITNESS: Yes. 12 MS. YOUNG: Q. Did you agree with that 13 statement at the time of Ms. Clark's implant in June 14 of 2003, if you remember? 15 MR. GROVES: Object to form. Calls for 16 speculation. Lacks foundation. 17 THE WITNESS: I would say yes. 18 MS. YOUNG: Q. In your opinion, Doctor, is 19 the TVT an important treatment option that should be 20 available to women and surgeons? 21 A. Yes. 22 Q. Would you agree that the TVT is the best 23 studied procedure for the treatment of SUI? 24 MR. GROVES: Object to form. Lack of 25 foundation.</p>

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1 THE WITNESS: Well, I think best is not the  
2 best word.  
3 MS. YOUNG: Q. Okay.  
4 A. It is extensively studied, and so are a lot  
5 of other midurethral mesh, polypropylene mesh slings,  
6 yes.  
7 Q. And I understand your hesitation in comparing  
8 it to other products and respect that, so let me just  
9 rephrase it a little bit.  
10 Are you comfortable with the level of study  
11 and testing done with the TVT product?  
12 A. Yes.  
13 MR. GROVES: Object to form.  
14 MS. YOUNG: Q. And you've already testified  
15 that the TVT is a less invasive surgical procedure  
16 than the Burch; is that correct?  
17 A. Yes.  
18 Q. And, Doctor, in your hands have your patients  
19 had a good clinical experience with the TVT?  
20 A. Yes.  
21 Q. And have you found in your experience that  
22 the benefits of TVT have outweighed the potential  
23 risks of using it?  
24 A. Yes.  
25 Q. In your experience have you found the TVT

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1 sling to be a safe and effective treatment option?  
2 A. Yes.  
3 Q. Okay.  
4 I think we're on Exhibit No. 5.  
5 (Whereupon Defendant's  
6 Exhibit 5 was marked for  
7 identification.)  
8 MS. YOUNG: Q. Doctor, I'm going to hand  
9 you what's been marked as Exhibit 5 to your  
10 deposition.  
11 It's titled, "Potential Risks of Non-Mesh  
12 Surgical" -- I'm sorry, "Non-Mesh Stress Urinary  
13 Incontinence Surgery."  
14 If you would take a look at those and read  
15 over the list.  
16 Are you familiar with what's listed on this  
17 exhibit as being potential risks of surgery to treat  
18 SUI even when a synthetic mesh is not used?  
19 A. Yes. This is a very comprehensive list.  
20 Q. And were you aware of each of these potential  
21 risks in non-mesh SUI surgeries at the time that you  
22 did Ms. Clark's surgery?  
23 A. Yes, I was.  
24 Q. I'm going to hand you next what's been marked  
25 as Exhibit 6 to your deposition.

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1 (Whereupon Defendant's  
2 Exhibit 6 was marked for  
3 identification.)  
4 MR. GROVES: Object to form. Sorry. I was  
5 on mute there.  
6 Counsel, what's the date of that document,  
7 Exhibit 5?  
8 MS. YOUNG: There is no date.  
9 MR. GROVES: Okay. And that was the non-mesh  
10 one?  
11 MS. YOUNG: Yes. Correct.  
12 Are you okay, Doctor. Do you need to take a  
13 break?  
14 THE WITNESS: One second.  
15 (Whereupon a conversation  
16 was held off the record.)  
17 MS. YOUNG: Q. If you would take a look at  
18 what's been marked as Exhibit 6 to your deposition.  
19 And you will see that it has on the left side the same  
20 list of risks that was listed on number 5 --  
21 A. Okay. All right.  
22 Q. -- as risks associated with non-mesh  
23 surgeries to treat stress urinary incontinence.  
24 And then on the right there are a list of  
25 risks associated with mesh surgeries to treat SUI.

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1 And my question is are you familiar with each  
2 of the lists listed on the right as being a risk  
3 associated with the mesh SUI surgery?  
4 A. Yes, they are identical lists, and it makes  
5 perfect sense that they would be.  
6 Q. Okay.  
7 And were you aware of these as risks  
8 associated with a mesh SUI surgery at the time of  
9 Ms. Clark's procedure in 2003?  
10 A. Yes.  
11 Q. At the time of Ms. Clark's procedure were you  
12 aware that acute or chronic pain with intercourse was  
13 a risk of a mesh SUI surgery?  
14 And I apologize it seems tedious, but I'm  
15 going to need to ask about each one.  
16 A. Well, then it's yes to each one.  
17 Q. Okay. This will go quickly then.  
18 Were you aware at the time of Ms. Clark's  
19 surgery that acute or chronic pain was a risk of mesh  
20 SUI surgery?  
21 A. Yes.  
22 Q. Were you also aware that vaginal scarring was  
23 a risk of the mesh SUI surgery?  
24 A. Yes.  
25 You really have to go through each one of

<p style="text-align: right;">Page 42</p> <p>1 these?</p> <p>2 Q. I apologize. I'm told to. Yes.</p> <p>3 A. I can read the list, and it's yes to all of</p> <p>4 these. I was aware.</p> <p>5 Q. Let me just read them all and have you</p> <p>6 respond.</p> <p>7 Were you aware at the time that infection was</p> <p>8 a risk of a mesh SUI surgery?</p> <p>9 A. Yes.</p> <p>10 Q. Were you aware at the time of urinary</p> <p>11 problems, including frequency, urgency, dysuria,</p> <p>12 retention, or obstruction, and incontinence as a risk</p> <p>13 of a mesh SUI surgery?</p> <p>14 A. Yes.</p> <p>15 Q. Were you aware of organ or nerve damage as a</p> <p>16 risk to a mesh SUI surgery?</p> <p>17 A. Yes.</p> <p>18 Q. Were you aware of bleeding as a risk to a</p> <p>19 mesh SUI surgery?</p> <p>20 A. Yes.</p> <p>21 Q. Were you aware of wound complications as</p> <p>22 well?</p> <p>23 A. Yes.</p> <p>24 Q. And inflammation?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 44</p> <p>1 A. Yes.</p> <p>2 Q. And lastly, were you aware of contraction or</p> <p>3 shrinkage of tissues as a risk related to a mesh SUI</p> <p>4 surgery?</p> <p>5 A. Yes.</p> <p>6 Q. Doctor, when you performed the procedure on</p> <p>7 Ms. Clark, would the TVT have come in packaging?</p> <p>8 A. Yes. Of course.</p> <p>9 Q. And does it include instructions for use in</p> <p>10 that packaging? An IFU or a document listing</p> <p>11 instructions for its use, if you know?</p> <p>12 A. I don't recall.</p> <p>13 Q. Okay.</p> <p>14 Do you recall --</p> <p>15 A. I would open the package, but I don't recall</p> <p>16 if there was an instruction pamphlet or sheet. I</p> <p>17 don't know.</p> <p>18 Q. Would you rely on a set of instructions that</p> <p>19 came within the product to teach you how to do the</p> <p>20 procedure?</p> <p>21 A. No.</p> <p>22 Q. Would you rely on a set of instructions that</p> <p>23 came with the product to inform you of potential risks</p> <p>24 or side effects?</p> <p>25 A. No.</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. And fistula formation?</p> <p>2 A. Yes.</p> <p>3 Q. And neuromuscular problems?</p> <p>4 A. Yes.</p> <p>5 Q. Were you aware of one or more surgeries to</p> <p>6 treat an adverse event as a potential risk of a SUI</p> <p>7 surgery?</p> <p>8 A. Yes.</p> <p>9 Q. And were you also aware of recurrence or</p> <p>10 failure?</p> <p>11 A. Yes.</p> <p>12 Q. Were you aware of foreign body response as a</p> <p>13 risk to a mesh SUI surgery?</p> <p>14 A. Yes. It's not worded properly. But yes.</p> <p>15 Q. Okay.</p> <p>16 And how would you word it differently?</p> <p>17 A. Well, you're asking a -- you're asking about</p> <p>18 mesh in general. And so, yes, with some mesh that is</p> <p>19 definitely true. But with a monofilament</p> <p>20 polypropylene it was -- a foreign body reaction would</p> <p>21 be pretty obscure.</p> <p>22 Q. Okay. Thank you for that clarification,</p> <p>23 Doctor.</p> <p>24 Were you aware of erosion, exposure or</p> <p>25 extrusion of mesh as risks of a mesh SUI surgery?</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Do you know for sure whether or not you ever</p> <p>2 read the instructions for use that accompany a TVT</p> <p>3 package?</p> <p>4 A. I was very well aware of how to perform the</p> <p>5 procedure. That's like asking would I open the book</p> <p>6 before every surgery to read about it. But, yes, I</p> <p>7 had read the instructions. I had memorized the</p> <p>8 instructions. I had performed many of these</p> <p>9 procedures. So I would not have read that prior to</p> <p>10 each individual surgery.</p> <p>11 Q. Doctor, one of the allegations in this</p> <p>12 lawsuit is that if all of the risks listed in</p> <p>13 Exhibit 6 had been included word for word in the</p> <p>14 instructions for use inside the TVT package that that</p> <p>15 would have changed your decision to prescribe the TVT</p> <p>16 for Ms. Clark.</p> <p>17 If each of those had been included in the TVT</p> <p>18 for the particular package that you would have opened</p> <p>19 and used with Ms. Clark, would that have had any</p> <p>20 impact on your decision to prescribe that product for</p> <p>21 her?</p> <p>22 MR. GROVES: Object to the narrative. Object</p> <p>23 to the form of the question.</p> <p>24 THE WITNESS: I don't really understand your</p> <p>25 question to be honest with you.</p>



<p style="text-align: right;">Page 46</p> <p>1 MS. YOUNG: Q. Okay.</p> <p>2 Is it fair to say that since you did not rely</p> <p>3 on the IFU in making your medical decision to</p> <p>4 prescribe the TVT, that changes to the wording within</p> <p>5 the IFU would have had no effect on your medical</p> <p>6 decision to prescribe the TVT?</p> <p>7 MR. GROVES: Object to the form of the</p> <p>8 question. Object to the question as lacking in</p> <p>9 foundation. I also think the question might have</p> <p>10 misstated the Doctor's testimony.</p> <p>11 Subject to that, Doctor, you can answer if</p> <p>12 you can.</p> <p>13 THE WITNESS: I don't know how to answer</p> <p>14 that. That would be like saying did I open the PDR</p> <p>15 from five years ago or today and look up a drug and it</p> <p>16 had a new list of complications, and did I memorize</p> <p>17 that list, and the answer would be no.</p> <p>18 I know how to use the product or the drug.</p> <p>19 I'm familiar with it. And if I use it repetitively, I</p> <p>20 would assume I'm still very familiar with it.</p> <p>21 MS. YOUNG: Q. And regardless of what was</p> <p>22 printed in the IFU, you were already aware of all the</p> <p>23 risks listed on Exhibit 6, correct?</p> <p>24 A. Yes.</p> <p>25 Q. Yes.</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. And what was the basis of your decision to</p> <p>2 not -- to not have scarring be a focus of the list of</p> <p>3 complications that you included in your article?</p> <p>4 MR. GROVES: Object to form.</p> <p>5 THE WITNESS: I don't know how to answer</p> <p>6 that.</p> <p>7 MS. YOUNG: Q. Did you consider -- well,</p> <p>8 let me ask you this.</p> <p>9 If a patient is complaining of pain with deep</p> <p>10 thrusts or insertion of the penis within the vagina,</p> <p>11 would you relate that to scarring from a TVT implant</p> <p>12 procedure?</p> <p>13 MR. GROVES: Object to form. Lack of</p> <p>14 foundation.</p> <p>15 MS. YOUNG: Q. You can answer.</p> <p>16 A. That would be very patient specific. In some</p> <p>17 cases maybe. In some cases, no.</p> <p>18 Q. Doctor, I'm going to hand you now what's been</p> <p>19 marked as Exhibit 7 to the deposition.</p> <p>20 (Whereupon Defendant's</p> <p>21 Exhibit 7 was marked for</p> <p>22 identification.)</p> <p>23 MS. YOUNG: Q. And, Counsel, these are the</p> <p>24 clinic records that we were discussing. It may have</p> <p>25 been before we went on the record. But the Bates</p>
<p style="text-align: right;">Page 47</p> <p>1 That's what we went through in tedious</p> <p>2 detail; is that right?</p> <p>3 A. Okay. Yes.</p> <p>4 Q. Yes. All right.</p> <p>5 A. And I've actually published a paper on the</p> <p>6 complications of incontinence procedures, and this</p> <p>7 is -- many of these are listed in that paper. So I'm</p> <p>8 very well aware.</p> <p>9 Q. In the paper that you have published related</p> <p>10 to the complications of this type of procedure, was</p> <p>11 the risk of dyspareunia or painful sex included?</p> <p>12 A. Yes.</p> <p>13 Q. Was the list of retention of urine or</p> <p>14 problems emptying the bladder included?</p> <p>15 A. Yes.</p> <p>16 Q. Was the risk of vaginal scarring included?</p> <p>17 A. Not directly.</p> <p>18 Q. And why is that?</p> <p>19 A. It was a review of literature regarding the</p> <p>20 complications, and the specific word "scarring," I</p> <p>21 don't recall it being used specifically as a</p> <p>22 complication.</p> <p>23 Q. Does the surgery to implant a TVT result in</p> <p>24 any scarring?</p> <p>25 A. All surgery results in some scarring.</p>	<p style="text-align: right;">Page 49</p> <p>1 numbers began with CLARKM_ABC_MDR00028.</p> <p>2 Doctor, if you would, can you tell me the</p> <p>3 date it appears you first saw Ms. Clark.</p> <p>4 A. I'd have to look through here. I don't know.</p> <p>5 This is not my writing.</p> <p>6 This is my writing.</p> <p>7 I have a form here, initial exam, and it's</p> <p>8 dated 11/27/2001.</p> <p>9 Q. Okay.</p> <p>10 And what were Ms. Clark's chief complaints at</p> <p>11 the time?</p> <p>12 A. I wrote, "Chief complaint. Bladder problems,</p> <p>13 frequency, occasional leaking, two periods this month,</p> <p>14 medium flow, was irregular."</p> <p>15 And then I wrote, "Menstrual irregularity,</p> <p>16 controlled with a medication for two years. This</p> <p>17 month two heavy cycles."</p> <p>18 So menstrual irregularity and incontinence</p> <p>19 looks like the initial -- at the initial visit.</p> <p>20 Q. Okay.</p> <p>21 And on the next page is there a diagnosis</p> <p>22 there?</p> <p>23 A. Yes. Menorrhagia. And stress urinary</p> <p>24 incontinence.</p> <p>25 Q. And if you would, does it look like she came</p>



<p style="text-align: right;">Page 50</p> <p>1 back about a year later, November 12th, 2002?</p> <p>2 A. Looks that way. But she had missed -- well,</p> <p>3 never mind. There's something written here about</p> <p>4 canceled office appointments.</p> <p>5 11/12/2012 an establish patient visit, it</p> <p>6 likes that's the next visit, yes.</p> <p>7 Q. Okay.</p> <p>8 And what were her complaints at that time?</p> <p>9 A. The same. Incontinence and irregular</p> <p>10 periods.</p> <p>11 Q. And on the next page is there a diagnosis?</p> <p>12 A. Dysfunctional uterine bleeding, which again</p> <p>13 is menstrual irregularity, and stress urinary</p> <p>14 incontinence. And I put in question mark, "a mixed</p> <p>15 incontinence."</p> <p>16 Q. For the ladies and gentlemen of the jury,</p> <p>17 what does mixed incontinence mean?</p> <p>18 A. So to divide incontinence into three or maybe</p> <p>19 four different subtypes, if a patient predominantly</p> <p>20 strains, like with a cough or a laugh or a lifting</p> <p>21 something, and they leak urine, that would usually</p> <p>22 be -- get a diagnosis of stress urine incontinence.</p> <p>23 If a patient has trouble holding urine in the</p> <p>24 bladder because the bladder spasms, then that may</p> <p>25 indicate a detrusor overactivity or a -- which is not</p>	<p style="text-align: right;">Page 52</p> <p>1 A. Yes.</p> <p>2 Q. And what did she indicate in this</p> <p>3 questionnaire?</p> <p>4 A. She indicated that she was leaking urine</p> <p>5 often, that she usually needed to know where a</p> <p>6 bathroom was located because she would have sudden</p> <p>7 urges to urinate. And sometimes she didn't make it to</p> <p>8 the bathroom.</p> <p>9 She wasn't wearing protective clothing at</p> <p>10 that time. I don't know the date of this. And that</p> <p>11 she was getting up more, either two times a night or</p> <p>12 more. But that wasn't a constant thing. It was she</p> <p>13 wrote sometimes.</p> <p>14 Q. Okay.</p> <p>15 If you go to a few more pages, there's a</p> <p>16 document titled, "Urogynecology History</p> <p>17 Questionnaire." That's dated May 16th of 2003.</p> <p>18 A. Mine doesn't have a date.</p> <p>19 Q. Yeah, there's one without a date and one past</p> <p>20 it that does have a date.</p> <p>21 A. Okay.</p> <p>22 Q. Do you see the one with the date? The number</p> <p>23 at the bottom is 107.</p> <p>24 A. Yes.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 51</p> <p>1 a stress incontinence.</p> <p>2 In some cases the two actually may coexist,</p> <p>3 and that would be a mixed type of incontinence.</p> <p>4 Q. Thank you.</p> <p>5 A. I'm sure you've heard this before.</p> <p>6 Q. Well, the jury hasn't.</p> <p>7 A. Okay.</p> <p>8 Q. So it's very helpful. I assure you.</p> <p>9 What was your plan at that time?</p> <p>10 A. Well, nothing definitive, but I wrote for the</p> <p>11 dysfunctional uterine bleeding an ultrasound and</p> <p>12 possibly an endometrial biopsy.</p> <p>13 For the incontinence, further workup, which</p> <p>14 would include urodynamic testing and a cystoscopy to</p> <p>15 look in the bladder. And, of course, prior to that a</p> <p>16 urinalysis to make sure there is no infection.</p> <p>17 And then to I guess to keep focus on the</p> <p>18 problem, since it had been existing for well over a</p> <p>19 year, possibility of a laparoscopic-assisted vaginal</p> <p>20 hysterectomy, which I wrote LAVH. And then I rarely</p> <p>21 did this. I don't know why I wrote, but</p> <p>22 radiofrequency bladder neck suspension was discussed.</p> <p>23 Q. Okay.</p> <p>24 And on the next page is there a patient</p> <p>25 questionnaire that Ms. Clark filled out?</p>	<p style="text-align: right;">Page 53</p> <p>1 At that time there's a question number 15</p> <p>2 that asks if she loses urine by spurts during severe</p> <p>3 coughing, sneezing, vomiting or laughing.</p> <p>4 A. She wrote sometimes with laughing.</p> <p>5 Q. Okay.</p> <p>6 And then on the next page is there a question</p> <p>7 29, if you would read that question for me, please.</p> <p>8 A. "Is your urinary problem bad enough that you</p> <p>9 would request surgery to fix it?"</p> <p>10 And she wrote, "Yes."</p> <p>11 Q. Okay.</p> <p>12 And that is May of 2003.</p> <p>13 If you will go two more pages to document --</p> <p>14 it has 87 at the bottom. Might be three more pages.</p> <p>15 A. Yes.</p> <p>16 Q. What do you see there?</p> <p>17 A. Okay. So this was a urinary -- excuse me, a</p> <p>18 urodynamic report. And so she voided normally with a</p> <p>19 normal flow rate.</p> <p>20 The system metrogram portion showed that she</p> <p>21 had a normally compliant bladder, and it held an</p> <p>22 adequate amount of urine. And when she strained, she</p> <p>23 demonstrated stress urinary incontinence.</p> <p>24 There was no evidence of detrusor spasms, and</p> <p>25 so the interpretation was stress urinary incontinence.</p>

<p style="text-align: right;">Page 54</p> <p>1 Q. And as a result of the stress urinary 2 incontinence and her other gynecological issues that 3 she was having, did you recommend surgery at that 4 time? 5 A. I did. 6 Q. Okay. 7 If you would -- 8 A. I don't recall the conversation, but I wrote, 9 "Laparoscopic-assisted vaginal hysterectomy/sling." 10 So I'm pretty sure given the way I practiced 11 that, given this information and her questionnaire 12 answers, that I counseled her that removing her uterus 13 and supporting her bladder would probably correct 14 these issues. 15 Q. Thank you, Doctor. 16 If you will turn to Bates label page 40 at 17 the bottom. 18 A. I have to tell you this. I'm looking back. 19 This is nice and thorough. This is good. 20 Here we go. 21 Q. It should be -- okay. And what is this 22 document? 23 A. This looks like her preoperative history and 24 physical. 25 Q. And under the history section, at the last</p>	<p style="text-align: right;">Page 56</p> <p>1 procedures, and also the way she heals. 2 Again, all surgeries are fraught with 3 potential complications, and residual pain is 4 certainly something that -- you know, pain, a wound 5 complication, infection, I mean these can happen with 6 any surgery. 7 So there would be a pretty generic 8 discussion, pretty rehearsed actually, about all of 9 these possible complications. 10 And a lot of patients would ask, well, how 11 often. And the answer would have been not very often. 12 And then they may ask, and in my hands how 13 many have I done. And I would tell them hundreds. 14 And how often do I see complications, and I would 15 probably tell them one or two out of a hundred would 16 come back with some sort of complication. 17 I would be honest with them and tell them, 18 yes, I've had to remove a sling or I've had to -- at 19 that point I was also removing slings that other 20 doctors were putting in because of my specialty 21 practice. So I would tell them that I've seen some 22 pretty nasty things and -- but that I would also be 23 checking during the procedure to make sure that the 24 sling was in the proper location, that it hadn't -- to 25 the best of my knowledge it hadn't snagged some other</p>
<p style="text-align: right;">Page 55</p> <p>1 sentence, does it indicate that the risk and benefits 2 of surgery were thoroughly discussed with Ms. Clark? 3 A. Yes. 4 Q. And I understand that you don't have an 5 independent memory of this particular patient after 6 all this time; is that right? 7 A. I do not. 8 Q. What would your informed consent discussion 9 for the TVT procedure specifically have involved with 10 a typical patient in 2003? 11 A. I would have definitely discussed some of the 12 complications listed on your potential risks Exhibit 13 No. 6. 14 Q. Okay. Thank you. 15 A. It's a rather focused discussion about the 16 way the procedure is done, the path of the trocars, 17 and the potential for injury, potential for bleeding, 18 the potential for failure, which is not really listed 19 here. These procedures don't always work. 20 Well, I guess it is here. Recurrence of 21 failure. Excuse me. 22 Pain after the procedure, mesh extrusion, 23 nerve pain, the possibility of having to remove the 24 mesh if there were complications. Certainly pain, 25 which could be from the combination of these</p>	<p style="text-align: right;">Page 57</p> <p>1 tissue, like there's been reports of bowel being 2 pulled into the procedure. 3 I mean, obviously I would let them know that 4 there are some pretty horrendous potential 5 complications. But I would also reassure them that 6 that had never happened to me and I didn't anticipate 7 it would. 8 And then, of course, that conversation would 9 have occurred probably at more than one occasion 10 because at the urodynamics, once we have a diagnosis, 11 we would talk about the options. 12 And then, of course, prior to surgery the 13 patient needs to sign their consent, and there would 14 be an opportunity to discuss again what we're doing 15 and why we're doing it. 16 And as I guess as you can see from my 17 charting here, you know, I was trying to put all the 18 pieces in place. And so I would -- I -- I'm actually 19 a surgeon who is very -- I'm quite a stickler for 20 patient's being well informed. 21 Now -- 22 Q. Thank you, Doctor. 23 A. -- discussed thoroughly is all I put, but 24 there was a lot more to that discussion. 25 Q. I understand.</p>

<p style="text-align: right;">Page 58</p> <p>1 If you'll turn to page 45 at the end. I'm  2 going to need to move just a little more quickly.  3 A. Sure.  4 Q. Because I only have an hour and a half with  5 you, and I'm going to reserve some of my time for the  6 end.  7 But is this your report of operation?  8 A. It is.  9 Q. And is that June 30th of 2003?  10 A. It is.  11 Q. And if you could explain in laymen's terms  12 what you did in this surgery for Ms. Clark.  13 A. I removed her uterus using a laparoscopic  14 approach as well as a vaginal approach. I removed  15 some implants. And I placed the sling and checked its  16 location with a cystoscope.  17 Q. What kind of implants did you remove?  18 A. Well, I wrote endometriotic implants. I'd  19 have to look through here to see. Which turned out to  20 be scar tissue.  21 Q. And what is endometriosis?  22 A. Well, this wasn't endometriosis.  23 Q. Oh, okay.  24 What are endometriotic implants?  25 A. This was probably -- and, again, I don't have</p>	<p style="text-align: right;">Page 60</p> <p>1 procedure?  2 A. It looks that way.  3 Q. And did she see you on August 20th of 2003?  4 A. She did.  5 Q. And what is it that your records say about  6 that visit?  7 A. She came in with some frequency of urination.  8 And it looks like she was having some mild retention.  9 And I talked to her about self-catheterizing  10 to see if this would resolve or to do what's called a  11 ureterolysis.  12 Q. Okay.  13 And when it says, "There's a small band of  14 tightness on the right aspect of the urethra and I  15 think that needs to be released," what does that  16 mean?  17 A. Specifically to her -- I'm sure I'm  18 summarizing from the exam that it just didn't feel as  19 supple as you might expect, and it may have -- it felt  20 tighter. And I didn't write here that it was tender,  21 but I would assume it's a tender area as well.  22 Q. Okay. If you can turn to page 62.  23 Is that the history and physical?  24 A. It is.  25 Q. On August 28, 2003?</p>
<p style="text-align: right;">Page 59</p> <p>1 an independent recollection. But I wrote here,  2 "Careful inspection revealed multiple areas of  3 fibrosis and endometriotic implants."  4 So they were probably red or black or  5 implants that were causing some sort of tissue  6 distortion or scarring.  7 And so I removed them and sent them to  8 pathology.  9 Q. And are you able to tell where the scarring  10 was from your report?  11 A. Multiple areas. So I didn't -- I don't think  12 I specifically stated where.  13 There was quite a bit of scarring in the  14 right ovarian fossa. So in the right side above the  15 ureter where the ovary would sit. I wrote here a  16 large area of fibrosis with a possible implant of  17 endometriosis was incised with electrocautery  18 scissors.  19 Because to take the uterus out and then leave  20 her ovaries but leave active endometriosis would  21 probably lead to further therapy, further surgery, so  22 I removed the scar tissue at that point.  23 Q. Okay.  24 And, Doctor, if you could turn to page 93.  25 Did you continue to follow Ms. Clark after her</p>	<p style="text-align: right;">Page 61</p> <p>1 A. It is.  2 Q. And what does it say there in the history  3 section?  4 A. That she had developed retention, and that  5 the sling may be too snug. And that she had been  6 self-catheterizing, but the problem persisted.  7 So due to the persistent retention she  8 requested that I go ahead and release the sling, which  9 is called ureterolysis.  10 Q. Thank you.  11 Is the risk that the placement may be too  12 snug, was that a known risk of the procedure at the  13 time?  14 A. Yeah. For the TVT it actually was because of  15 the angle of insertion under the urethra. And so  16 compared to other types of slings, it actually was.  17 Turns out that it was a little more common  18 with a TVT.  19 It's also a little more common in somebody  20 who underwent -- common in somebody who is asleep  21 during the procedure. And -- but, yes, this is a  22 known complication of a TVT.  23 Q. When you say common to the procedure, do you  24 mean the fact she also had a hysterectomy at the same  25 procedure?</p>

<p style="text-align: right;">Page 62</p> <p>1 A. Yes. And she was asleep for that.</p> <p>2 Q. Okay.</p> <p>3 And then did you perform a revision on</p> <p>4 August 28, 2003, page 60?</p> <p>5 A. Well, not a revision.</p> <p>6 Q. Okay.</p> <p>7 A. I released -- I released the sling slightly.</p> <p>8 It looks like I did it under local.</p> <p>9 So I basically opened up the area under the</p> <p>10 sling and made a small snip in it to just give it a</p> <p>11 little release, which is usually very effective, and</p> <p>12 then I closed the vaginal tissue.</p> <p>13 Q. Okay.</p> <p>14 And, Doctor, I'm going to need to reserve the</p> <p>15 rest of my time. So let's take a quick break at this</p> <p>16 point.</p> <p>17 VIDEOGRAPHER: All right. We are going off</p> <p>18 the record at 12:31 p.m.</p> <p>19 (Recess taken.)</p> <p>20 VIDEOGRAPHER: All right. We are back on the</p> <p>21 record at 12:42 p.m.</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 64</p> <p>1 defendants Ethicon Corporation; is that correct?</p> <p>2 A. Yes, I'll agree with you.</p> <p>3 Q. Okay.</p> <p>4 Kind of at the outset what I like to do at</p> <p>5 some of these depositions, Doctor, is make clear that</p> <p>6 in no way, shape or form has my client made any sort</p> <p>7 of complaint or legal allegations against you in this</p> <p>8 case. Okay? Is that understood?</p> <p>9 A. Well, that's nice to hear.</p> <p>10 Q. Okay.</p> <p>11 So her lawsuit, in effect, it's not about</p> <p>12 you. It's about a product. Is that understood?</p> <p>13 A. Yes, that's understand.</p> <p>14 Q. Okay.</p> <p>15 (Whereupon a conversation</p> <p>16 was held off the record.)</p> <p>17 MR. GROVES: Q. Thanks again to every in</p> <p>18 the room for putting up with me by joining by phone.</p> <p>19 I appreciate it.</p> <p>20 I also have a one and three-year-old at home</p> <p>21 that probably appreciate it as well, I hope.</p> <p>22 Doctor, defense counsel asked you some</p> <p>23 questions kind of about your background. And I was</p> <p>24 kind of wanting to get a better understanding. And</p> <p>25 she probably did a good job going over this. But I</p>
<p style="text-align: right;">Page 63</p> <p>1 EXAMINATION</p> <p>2</p> <p>3 BY MR. GROVES:</p> <p>4 Q. Good afternoon, Doctor, Counsel. I</p> <p>5 understand it's a little bit after the lunch hour</p> <p>6 there. Thank you for your time dealing with us today,</p> <p>7 Doctor.</p> <p>8 My name is Rob Groves, and I, of course, as I</p> <p>9 previously mentioned, am the attorney for the</p> <p>10 plaintiff, Ms. Marabeth Clark, in this case. This is</p> <p>11 a lawsuit filed by Ms. Clark against Ethicon, the</p> <p>12 maker of a TVT sling that is the subject matter of</p> <p>13 this lawsuit.</p> <p>14 Is that understood, Doctor?</p> <p>15 A. It is understood.</p> <p>16 Q. Okay.</p> <p>17 And you are -- I don't believe we made any</p> <p>18 sort of an exhibit of it.</p> <p>19 You at some point today, you or your office</p> <p>20 received what we as attorneys like to call Notice of</p> <p>21 Deposition; is that correct?</p> <p>22 A. Probably, yes.</p> <p>23 Q. Okay. That sounds good enough for me.</p> <p>24 Doctor, is it your understanding that that</p> <p>25 Notice of Deposition was issued by counsel for</p>	<p style="text-align: right;">Page 65</p> <p>1 want to get a slight better understanding about some</p> <p>2 of your relevant work history back in around the 1996,</p> <p>3 1997 time frame.</p> <p>4 I understand that you said that you said that</p> <p>5 you had some training experience with a Dr. Olmsted;</p> <p>6 is that correct?</p> <p>7 A. Yeah. A brief visit to him to learn about</p> <p>8 this procedure, yes.</p> <p>9 Q. Okay.</p> <p>10 And did I understand your testimony correctly</p> <p>11 that you don't recall what year that was?</p> <p>12 A. I don't.</p> <p>13 Q. But it was sometime say after 1996?</p> <p>14 A. I don't recall.</p> <p>15 Q. Okay.</p> <p>16 And it was about a week-long course in</p> <p>17 Sweden?</p> <p>18 A. Yeah, a couple -- yeah, with travel it was</p> <p>19 about a five-day trip.</p> <p>20 Q. Okay.</p> <p>21 And was it a cadaver type course?</p> <p>22 A. There was a portion of it was cadaver and</p> <p>23 portion was live.</p> <p>24 Q. Okay.</p> <p>25 And do you have any idea, was the trip</p>

<p style="text-align: right;">Page 66</p> <p>1 sponsored by a manufacturer of mesh product?</p> <p>2 A. That's a good question.</p> <p>3 I don't recall, but it's possible. Yeah.</p> <p>4 Q. And, Doctor, I'll just say kind of I think as</p> <p>5 counsel probably already alluded to. If you don't</p> <p>6 specifically recollect or something like that, I</p> <p>7 understand that we are talking about something that</p> <p>8 happened sometime ago.</p> <p>9 A. Yeah. And I took a lot of trips to Europe</p> <p>10 because of -- for different reasons, professional and</p> <p>11 personal so...</p> <p>12 Q. Okay.</p> <p>13 Well, and that was kind of one of my next</p> <p>14 questions.</p> <p>15 I was wondering if you had ever traveled to</p> <p>16 any other places other than Sweden for training on</p> <p>17 things like a transvaginal mesh product?</p> <p>18 A. Not that I recall.</p> <p>19 Q. So is the trip to Sweden with Dr. Olmsted the</p> <p>20 only training that you've had on transvaginal mesh</p> <p>21 products for the treatment of stress urinary</p> <p>22 incontinence?</p> <p>23 A. Well, no, I had training in my residency.</p> <p>24 Q. I'm sorry, Doctor. I meant in regards to</p> <p>25 traveling to a destination to take a course of study</p>	<p style="text-align: right;">Page 68</p> <p>1 somebody realized I was there, and they said could you</p> <p>2 swing by and meet with so and so.</p> <p>3 And so I've actually had quite a bit of</p> <p>4 experience doing collegial work, and I don't recall --</p> <p>5 to be honest, I don't recall how this trip was put</p> <p>6 together.</p> <p>7 Q. Okay.</p> <p>8 And I don't necessarily need the particular</p> <p>9 details. All I'm trying to do is figure out if you</p> <p>10 were ever -- either attended a training as a trainee</p> <p>11 or a trainer that was essentially sponsored by a</p> <p>12 product manufacturer, a transvaginal mesh product</p> <p>13 manufacturer. That's all.</p> <p>14 A. I know I've been a trainee or trainer.</p> <p>15 Not -- a trainer.</p> <p>16 Q. Yes.</p> <p>17 A. Yes. Yes.</p> <p>18 Q. Okay.</p> <p>19 A. And with Olmsted it was a new procedure, so,</p> <p>20 yes, I was a trainee under those circumstances.</p> <p>21 Q. Okay.</p> <p>22 And you've also -- you said you've given</p> <p>23 literally hundreds of seminar type speeches and</p> <p>24 presentations; is that correct?</p> <p>25 A. That is true.</p>
<p style="text-align: right;">Page 67</p> <p>1 for TV mesh products for the treatment of stress</p> <p>2 urinary incontinence, is Sweden the only trip?</p> <p>3 A. Well, for my personal edification, probably.</p> <p>4 But I've also taught dozens of these types of courses</p> <p>5 for different procedures, and a lot of that required</p> <p>6 travel as well.</p> <p>7 Q. Okay.</p> <p>8 So as a student, if you will, Sweden was the</p> <p>9 only trip?</p> <p>10 A. Yeah, I'm not -- yeah, I don't know. I don't</p> <p>11 know that it was the only trip. It was the only trip</p> <p>12 to Sweden. I can recall that.</p> <p>13 Q. And do you have any recollection about how</p> <p>14 that trip was funded? Did you pay for it out of your</p> <p>15 own personal finances?</p> <p>16 A. I don't recall. I don't recall if I was</p> <p>17 already over there. I don't recall if it was</p> <p>18 partially sponsored. I don't recall.</p> <p>19 Q. Okay.</p> <p>20 A. I mean, I'll give you an example.</p> <p>21 I've done research for a couple of companies,</p> <p>22 and they would say something like, "Could you please</p> <p>23 go over to Munich and work on this, and we'll give you</p> <p>24 a ticket."</p> <p>25 Or I was doing work with the WHO, and</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. Okay.</p> <p>2 And does -- I'm assuming that those</p> <p>3 presentations could vary on a number of OB/GYN</p> <p>4 subjects; is that correct?</p> <p>5 A. Yes. It wasn't the same lecture over and</p> <p>6 over. There would be some variety.</p> <p>7 Q. Okay.</p> <p>8 To the best of your ability do you recall,</p> <p>9 would any of those presentations specify techniques,</p> <p>10 trends, things of that nature, hazardous issues,</p> <p>11 anything like that with regards to TVT products?</p> <p>12 MS. YOUNG: Object to form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 Maybe not specifically or only TVT, but I'm</p> <p>15 sure -- yes, TVT, would have been part of the subject</p> <p>16 matter.</p> <p>17 MR. GROVES: Q. Okay.</p> <p>18 And you also mentioned doing grand rounds.</p> <p>19 A. Yes.</p> <p>20 Q. Now, in your -- as a presenter -- and I'm</p> <p>21 completely foreign to this.</p> <p>22 As a presenter of the sort of information</p> <p>23 that you're doing, if you're doing a Grand Round, is</p> <p>24 that sort of a -- is that a bigger event deal to you</p> <p>25 than a regular presentation, or is there really no</p>



<p style="text-align: right;">Page 70</p> <p>1 distinction?</p> <p>2 A. Oh, I think in the academic world it's</p> <p>3 considered kind of a feather in the cap. But I've</p> <p>4 given lectures to 3,000 people at a conference which</p> <p>5 was not a grand rounds, which, you know, is quite a</p> <p>6 big -- that's quite a big audience.</p> <p>7 Q. Was any of these Grand Round type lectures,</p> <p>8 were they also concerned, at least a portion of them,</p> <p>9 TVT products?</p> <p>10 A. Some of them may have, yes.</p> <p>11 Q. And, Doctor, I wasn't quite clear.</p> <p>12 Do you know roughly when you did do your</p> <p>13 first, as the implanting physician, your first implant</p> <p>14 of any sort of mesh product for treatment of stress</p> <p>15 urinary incontinence in a female, roughly speaking</p> <p>16 what year that might have been?</p> <p>17 A. Maybe 1994 or so.</p> <p>18 Q. Okay.</p> <p>19 And I believe you said that you had done</p> <p>20 several hundred TVT procedures prior to Ms. Clark, and</p> <p>21 that would have been several hundred procedures</p> <p>22 starting back in roughly 1994 to about the time of</p> <p>23 Ms. Clark's operation in 2003?</p> <p>24 A. Yes. I think, yes.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 72</p> <p>1 go to more of the hospital administrative role as</p> <p>2 opposed to the implant or surgeon role. All those</p> <p>3 companies?</p> <p>4 A. Yeah, I would say all of those. If -- yeah.</p> <p>5 Depends if the hospital stocked them on the -- in the</p> <p>6 hospital. Not every product was carried by every</p> <p>7 hospital.</p> <p>8 Q. Okay.</p> <p>9 Doctor, I want to go through some of the</p> <p>10 things that you would use to kind of inform yourself</p> <p>11 about mesh products when you would be giving a</p> <p>12 presentation or anything like that.</p> <p>13 Would you rely upon medical journals?</p> <p>14 A. Yes, I would.</p> <p>15 Q. Would you rely upon discussions you had with</p> <p>16 colleagues?</p> <p>17 A. You mean passing on just stories or anecdotal</p> <p>18 stuff, usually not, no.</p> <p>19 Q. Okay.</p> <p>20 I'm assuming you would use your own clinical</p> <p>21 experience?</p> <p>22 A. Yes, I would.</p> <p>23 Q. Would you use your body of knowledge based</p> <p>24 upon other presentations that you either attended or</p> <p>25 presented at?</p>
<p style="text-align: right;">Page 71</p> <p>1 Do you currently use TVT slings to this</p> <p>2 day?</p> <p>3 A. No. I've stopped doing surgery.</p> <p>4 Q. I'm sorry. You said you stopped.</p> <p>5 When you stopped -- at the time you stopped</p> <p>6 doing surgery and kind of gone over to more of the</p> <p>7 kind of administrative hospital role, were you using</p> <p>8 TVT products then?</p> <p>9 A. Yes.</p> <p>10 Q. Do you recall to the best of your ability who</p> <p>11 the product was, product or products were manufactured</p> <p>12 by?</p> <p>13 A. You mean -- you asked for products. What do</p> <p>14 you -- what specifically do you mean?</p> <p>15 Q. Well, okay. This lawsuit is a Gynecare TVT</p> <p>16 sling product. And I guess my question is were you --</p> <p>17 do you know who the manufacturer of your mesh products</p> <p>18 were about the time you stopped doing surgery?</p> <p>19 A. Well, there was Johnson &amp; Johnson. I believe</p> <p>20 they still own Gynecare. There's Coloplast. There's</p> <p>21 AMS. There's Boston Scientific, but I rarely used</p> <p>22 those. Caldera. And there's a number of corporations</p> <p>23 that produce different slings that I have used.</p> <p>24 Q. Okay. And I guess I was trying to understand</p> <p>25 who you were using about the time that you decided to</p>	<p style="text-align: right;">Page 73</p> <p>1 A. Yes. I would have, yes.</p> <p>2 Q. In back around the time of 2003 when the</p> <p>3 implant procedure was performed on my client, were you</p> <p>4 also giving presentations and so forth at that point</p> <p>5 in time as well?</p> <p>6 A. Yes.</p> <p>7 Q. And would I be correct to presume that some</p> <p>8 of those presentations would, of course, have to deal</p> <p>9 with mesh sling implants and revision and so forth?</p> <p>10 A. Some of them, yes.</p> <p>11 Q. Back around that same time frame 2003, would</p> <p>12 you rely upon materials for mesh manufacturers when</p> <p>13 giving presentations about TVT products?</p> <p>14 A. Well, you used the word rely on. No. I</p> <p>15 might borrow some photographs or I might use tables of</p> <p>16 numbers that sort of summarize the literature. But,</p> <p>17 of course, it's my -- it would be my talk. I would</p> <p>18 rely on the information sort of in combination and I</p> <p>19 would use the information that was presented to me in</p> <p>20 different ways, yeah.</p> <p>21 Q. Certainly. And I don't want to get hung up</p> <p>22 on one word, but let me kind of rephrase.</p> <p>23 Would you consider information that was put</p> <p>24 forth by TVT manufacturers, say like Ethicon, in</p> <p>25 coming to whatever conclusions you needed to about</p>



<p style="text-align: right;">Page 74</p> <p>1 making a presentation or PowerPoint slides and so 2 forth?</p> <p>3 MS. YOUNG: Object to form.</p> <p>4 THE WITNESS: Like I said, I might borrow 5 some information or borrow a photograph, sure.</p> <p>6 MR. GROVES: Q. Okay.</p> <p>7 Would you discuss adverse events and warnings 8 and things like that back in 2003 at these 9 presentations?</p> <p>10 A. That usually wasn't the reason for the 11 presentation, so I don't recall.</p> <p>12 Q. Doctor, would you -- back in around 2003 13 would you ever have occasion to read any sort of Dear 14 Doctor letters or anything like that issued by mesh 15 manufacturers?</p> <p>16 A. I guess I would have the occasion, but I 17 can't -- I don't recall ever reading them, no.</p> <p>18 Q. Well, if a mesh manufacturer issued a Dear 19 Healthcare Provider letter or Dear Doctor letter to 20 the implanting physicians out there in the public, is 21 that something that if it were out there, would you at 22 least read it?</p> <p>23 MS. YOUNG: Object to form.</p> <p>24 THE WITNESS: I guess I have no idea. I 25 mean, I'm not sure what you're talking about. But I</p>	<p style="text-align: right;">Page 76</p> <p>1 Ms. Clark</p> <p>2 A. I have no way of knowing whether I read it 3 during that time period or not.</p> <p>4 I mean, I guess you're asking, so if a new 5 textbook on gynecologic surgery was published, would I 6 have read the new edition. I would have to say 7 probably not, or maybe. But I wouldn't reread an 8 instructional manual on something that hasn't changed.</p> <p>9 Q. No. And that's my point. That was kind of 10 the basis of my question. I think I maybe did a poor 11 job of asking.</p> <p>12 A. Okay.</p> <p>13 I think I have a pretty good memory. That's 14 what I'm trying to tell you.</p> <p>15 Q. I guess there's essentially a two-and-a-half 16 or three-year period where Ethicon, the manufacturer 17 of Mrs. Clark's TVT sling, had made what we call an 18 instructions for use, which are titled, "Instructions 19 of Use."</p> <p>20 And my question to you would be if at any, 21 not certainly prior to every surgery, but anytime 22 prior to Mrs. Clark's surgery in 2000 and 2003 you had 23 read Instructions for Use.</p> <p>24 MS. YOUNG: Object to form.</p> <p>25 THE WITNESS: What does that even matter.</p>
<p style="text-align: right;">Page 75</p> <p>1 guess yes, if there was some informational letter, I 2 would probably glance at it or read it, yes.</p> <p>3 MR. GROVES: Q. And, Doctor, kind of the 4 same question. In regards to IFU's, instructions for 5 use, I believe defense counsel might have asked you a 6 question or two about it.</p> <p>7 If I understood correctly, you testified that 8 you would read an instruction for use for a TVT 9 product, but you would not necessarily read it prior 10 to every single surgery you did. Is that a fair 11 characterization of your testimony?</p> <p>12 MS. YOUNG: Object to form.</p> <p>13 THE WITNESS: Yes, I would not reread 14 material over and over prior to every procedure. So, 15 no, I wouldn't.</p> <p>16 MR. GROVES: Q. Okay.</p> <p>17 So, for example, in this particular case we 18 had an implant surgery that was done in June of 2003. 19 And I may be -- I think I'm right on this. But the 20 relevant instructions for use that were in effect in 21 June of 2003 were issued sometime in 2000. At least 22 they're dated in 2000.</p> <p>23 Is it fair to say that sometime between 2000 24 and June of 2003 that you would have read the 25 instructions for use prior to your implant of</p>	<p style="text-align: right;">Page 77</p> <p>1 I'm sorry. I don't mean to be argumentative, but I 2 don't know what that matters.</p> <p>3 As a surgeon I -- yes, I probably would have 4 read -- I've written instructions for use for 5 different procedures. So I get it.</p> <p>6 And, yes, I probably did familiarize myself 7 with the procedure probably with something like one of 8 these monograms or an instructions for use. But I 9 have no recollection of when I would have read 10 something like that or to what extent.</p> <p>11 MR. GROVES: Q. Okay. Thanks, Doctor.</p> <p>12 And I don't mean to irk you or anything like 13 that, and I don't want to get to hyperspecific with my 14 questions.</p> <p>15 And I guess let me ask you kind of a 16 follow-up question to that.</p> <p>17 Have you ever done consulting work for a 18 product manufacturer, a mesh product manufacturer in 19 terms of consulting work for drafting instructions for 20 use or anything of that nature?</p> <p>21 A. Yes, I have.</p> <p>22 Q. Do you know what manufacturer or 23 manufacturers you have done consulting work for?</p> <p>24 A. For products?</p> <p>25 Q. Yes. Yes, sir, for mesh products.</p>

<p style="text-align: right;">Page 78</p> <p>1 A. Oh, for mesh products.</p> <p>2 Yes. I was the lead principle investigator</p> <p>3 of the international study on anterior elevate for</p> <p>4 AMS. And we've published two papers on that.</p> <p>5 I -- in fact, for that procedure I wrote the</p> <p>6 instructions of how to implant them.</p> <p>7 I believe I've done the same for Coloplast</p> <p>8 for one of their mesh sling devices.</p> <p>9 At the moment that's all I recall.</p> <p>10 Q. Okay.</p> <p>11 And sorry, Doctor, if I jump in there if</p> <p>12 there's kind of a dead space. I don't want to</p> <p>13 interrupt you. Just please tell me that you are not</p> <p>14 done answering my question.</p> <p>15 To the best of your knowledge did you ever do</p> <p>16 any consulting work for Ethicon in regards to any mesh</p> <p>17 products or anything like that?</p> <p>18 A. No, I didn't.</p> <p>19 The only consulting I did for Ethicon was to</p> <p>20 prepare a paper for some of their internal</p> <p>21 administrative positions, kind of a synopsis on the</p> <p>22 state of the art of reconstructive pelvic surgery and</p> <p>23 stress incontinence, which I gave to them. I don't</p> <p>24 remember exactly when. Maybe two-thousand-and- -- I</p> <p>25 don't remember when it was. In the mid 2000s.</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. Well, do you believe that the device -- the</p> <p>2 medical product manufacturer, the mesh manufacturer is</p> <p>3 in the best position to study its own device?</p> <p>4 A. No, not always. I think outside research is</p> <p>5 just as effective.</p> <p>6 Q. Do you believe at the time you recommended</p> <p>7 the TVT product to Mrs. Clark that the manufacturer</p> <p>8 Ethicon had adequately studied the product to</p> <p>9 determine that the product was both safe and</p> <p>10 effective?</p> <p>11 A. I do. Or available research showed that it</p> <p>12 was safe and effective in my opinion.</p> <p>13 Q. Did you believe that at the time you</p> <p>14 recommended the product to Mrs. Clark that the</p> <p>15 manufacturer had conducted proper trials to determine</p> <p>16 that its product was safe and effective?</p> <p>17 A. You're asking me whether industry sponsored</p> <p>18 research was sufficient for me to rely only on that as</p> <p>19 enough information. And I would say I don't really</p> <p>20 know how to answer that.</p> <p>21 I don't recall if the research -- the</p> <p>22 research that I would quote was industry sponsored or</p> <p>23 not.</p> <p>24 So I don't know whether it was -- whether the</p> <p>25 manufacturer had done the research adequately. I</p>
<p style="text-align: right;">Page 79</p> <p>1 That's -- and that was the only time I've</p> <p>2 ever done any consulting work for Ethicon.</p> <p>3 Q. Okay. Thank you, Doctor.</p> <p>4 Doctor, would you agree with me a mesh</p> <p>5 manufacturer is responsible for the safety of its</p> <p>6 product?</p> <p>7 A. No, I don't agree with that. I think that to</p> <p>8 a point once they are -- when they are manufactured,</p> <p>9 they need to be manufactured properly and safely, and</p> <p>10 they need to be sterile products. But once they are</p> <p>11 on the hospital's shelves, personally I don't think</p> <p>12 it's their responsibility anymore.</p> <p>13 Q. Doctor, do you agree in order to determine</p> <p>14 whether a medical device is safe and effective, the</p> <p>15 device must be adequately studied?</p> <p>16 A. I think that's a fair statement.</p> <p>17 Q. Do you agree that the best way to determine</p> <p>18 whether a medical device is safe and effective is for</p> <p>19 a manufacturer to conduct randomized controlled trials</p> <p>20 of the device?</p> <p>21 A. No. Randomized controlled trials of surgery</p> <p>22 are very, very difficult. And so cohorts studies,</p> <p>23 retrospective studies are -- I think are equally</p> <p>24 effective. It does not have to be a randomized</p> <p>25 controlled study.</p>	<p style="text-align: right;">Page 81</p> <p>1 don't know how to -- I don't know if that's the case</p> <p>2 or not. I would assume that they did or that they had</p> <p>3 collected enough information from other researchers to</p> <p>4 present that the data was compelling and convincing.</p> <p>5 Q. Well, let me ask kind of another way.</p> <p>6 If you had known at the time that the</p> <p>7 manufacturer had not -- at the time of your</p> <p>8 recommendation or your time of implant to Mrs. Clark</p> <p>9 that the manufacturer had not adequately studied its</p> <p>10 product to determine it was safe and effective, would</p> <p>11 you still have recommended the product to plaintiff?</p> <p>12 MS. YOUNG: Object to form. Lack of</p> <p>13 foundation.</p> <p>14 THE WITNESS: Yeah, that's kind of a</p> <p>15 misleading question.</p> <p>16 No, I -- I really don't know how to answer</p> <p>17 that to be perfectly honest with you.</p> <p>18 MR. GROVES: Q. Well, I'll just ask the</p> <p>19 court reporter to repeat my question.</p> <p>20 A. Okay.</p> <p>21 Q. Or I'll just go ahead and repeat it.</p> <p>22 If you had known at the time of implant or</p> <p>23 the time Mrs. Clark was needing an implant, I should</p> <p>24 say, that the manufacturer had not adequately studied</p> <p>25 its product to determine that it was safe and</p>

<p style="text-align: right;">Page 82</p> <p>1 effective, would you have gone ahead and recommended 2 it to Mrs. Clark?</p> <p>3 MS. YOUNG: Same objection.</p> <p>4 THE WITNESS: I told you I didn't rely on the 5 manufacturer's research, so, yes. The answer would be 6 yes. I would have still implanted it.</p> <p>7 But I have no idea what you mean by the 8 manufacturer and adequate research. I'm just still 9 stumped on that.</p> <p>10 MR. GROVES: Q. Would you consider research 11 data provided by the manufacturer?</p> <p>12 A. No, I would -- I told you earlier I relied on 13 my reading of the literature and my interpretation of 14 the literature. I didn't spend much time with Ethicon 15 or their representatives. And I certainly wouldn't 16 rely on them to convince me that something is 17 adequately studied or reliable. That was my job as 18 the surgeon.</p> <p>19 Q. Well, Doctor, one of the things that device 20 manufacturers such as Ethicon warn about these mesh 21 products is that if you are somebody who is pregnant 22 or becoming pregnant or thinking about becoming 23 pregnant, then you should either refrain or have a 24 discussion with your physician first about implanting 25 this product; is that correct?</p>	<p style="text-align: right;">Page 84</p> <p>1 product that you had implanted in Mrs. Clark?</p> <p>2 A. Specifically I don't believe so.</p> <p>3 Q. Is there any information or did Counsel give 4 you any information to show you that mesh 5 manufacturers are actually members of AUGS and pay 6 money to that organization?</p> <p>7 MS. YOUNG: Object to form. Lack of 8 foundation.</p> <p>9 THE WITNESS: What was that question again? 10 (Record read.)</p> <p>11 THE WITNESS: No. They -- Counsel, gave me 12 no information to that effect.</p> <p>13 But I sat on the executive committee of AUGS 14 as well as other organizations, and that's a common 15 practice to partner with manufacturers to offset the 16 costs of running annual meetings and whatnot. So 17 that's actually a very common practice.</p> <p>18 MR. GROVES: Q. Doctor, isn't it correct, 19 isn't it true that the statement that Counsel read 20 you, the names of authors of those statements are not 21 set forth anywhere in the AUGS documents that Counsel 22 gave you?</p> <p>23 A. It was drafted by three, five different 24 individuals on page three. All of whom I know.</p> <p>25 Q. I'm sorry. Did I interrupt you, Doctor?</p>
<p style="text-align: right;">Page 83</p> <p>1 A. Yeah. That's commonsensical, yes.</p> <p>2 Q. And that's information that's put out by the 3 manufacturer, correct?</p> <p>4 A. Yeah, I would imagine they would publish that 5 somewhere, yes.</p> <p>6 Q. And that's a conversation that I'm assuming 7 that you have with your mesh candidates, your patients 8 who are contemplating having a mesh implant prior to 9 implant, correct?</p> <p>10 A. Probably not. The average age is 53, which 11 is well beyond child-rearing age.</p> <p>12 Now, if they were 20, yes. But I probably 13 wouldn't put a mesh in a 20 year old.</p> <p>14 Q. Doctor, in front of you you have a AUGS 15 Physician Statement. I believe it's dated January 16 2014. That's Exhibit 4.</p> <p>17 A. Okay.</p> <p>18 I have it in front of me.</p> <p>19 MS. YOUNG: Can you hold on just a second, 20 Rob, so I can grab it.</p> <p>21 MR. GROVES: Sure.</p> <p>22 MS. YOUNG: Exhibit 4.</p> <p>23 Okay. I've got it. Thank you.</p> <p>24 MR. GROVES: Q. Doctor, anywhere in that 25 physician's statement does it mention the specific</p>	<p style="text-align: right;">Page 85</p> <p>1 A. No. No. Go ahead.</p> <p>2 Q. Doctor, are you aware that some of the 3 authors of these physician statements have been 4 deposited in product liability lawsuits?</p> <p>5 MS. YOUNG: Object to form. Lack of 6 foundation.</p> <p>7 THE WITNESS: I would have no way of knowing 8 that.</p> <p>9 MR. GROVES: Q. Were you aware that under 10 oath at least one AUGS author had stated that one of 11 the reasons for these physician statements was to be 12 used in litigation?</p> <p>13 MS. YOUNG: Object to form. Lack of 14 foundation.</p> <p>15 THE WITNESS: I would have no way of knowing 16 that.</p> <p>17 MR. GROVES: Q. Doctor, isn't it true that 18 in medicine there have been things called the gold 19 standard and later were proven not only to be a, 20 quote, unquote, "gold standard," but they were 21 actually abandoned procedures altogether?</p> <p>22 A. I would say that's true of almost any surgery 23 that hasn't stood the test of time. At one point the 24 Burch was the gold standard, but it got supplanted by 25 these mesh sling procedures.</p>

<p style="text-align: right;">Page 86</p> <p>1 Q. And last, defense counsel didn't walk you 2 through any of the references in these physician 3 statements to actually show you what the references 4 actually say, right? 5 A. No, she did not. 6 Q. Doctor, I want to take a look at Exhibit 5 7 and Exhibit 6. I believe that you might remember 8 that. It was kind of mesh, non-mesh chart that 9 defense counsel provided you. 10 A. Yeah. But I think I'm going to have to amend 11 one of my answers about specifically mentioning this 12 product because reference number 11 by Ward and Hilton 13 specifically mentions a randomized trial of 14 tension-free vaginal tape. So I guess it is mentioned 15 in this physician paper, or whatever this is called. 16 Q. Doctor, if you're looking at Exhibit 5 and 17 Exhibit 6, I just want to ask you a few kind of 18 follow-up questions. 19 Doctor, would you agree with me that each 20 pelvic surgery carries with it its own risk product 21 profile. 22 A. Yes. I think I could say yes to that. 23 Q. What -- would you kind of agree with me -- 24 kind of a similar question -- that each patient 25 undergoing some sort of pelvic surgery carries with</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. I'm sorry. Doctor, if you need to go back 2 and amend any of your answers, please let me know. 3 A. No. No. 4 Q. I was talking about Exhibits 5 and 6. 5 A. No. I got you. 6 Q. Okay. 7 A. So these lists, they do not mention specific 8 numbers, no. 9 Q. Well, I believe I asked about frequency, 10 severity and chronicity, but you said numbers. Do we 11 agree that they do not -- 12 A. Yeah. 13 Q. -- contain any of that information? 14 A. They do not, no. 15 Q. Do we agree that the chart does not include 16 any information about mesh fraying, roping, curling, 17 migrating? 18 A. No, it doesn't. 19 Q. It doesn't contain that information? 20 A. No, it does not. 21 Q. Okay. I'm sorry. I was just trying -- I 22 didn't want to have a double negative on the record 23 there. Sorry, Doctor. 24 A. Yeah, I actually -- I'm kind of surprised by 25 the question. I hadn't even -- I don't know. Those</p>
<p style="text-align: right;">Page 87</p> <p>1 them their own risk profile as well? 2 A. Yeah, that's probably a more accurate 3 statement. 4 Q. So the answer is yes? 5 A. Yes. 6 Q. Would you agree with me that as a result of 7 these things that the informed consent discussions for 8 pelvic surgeries is going to differ patient by 9 patient? 10 A. It should, yes. I mean, there's going to be 11 some generic overlap with and common discussions with 12 each patient. But there may be some tailored 13 discussions based on different patient factors, of 14 course. 15 Q. Okay. 16 And, Doctor, you'd agree with me the chart 17 does not include any information about frequency, 18 severity or chronicity of the risks or complications 19 noted, does it? 20 A. You mean Exhibit 7, the chart we looked at? 21 Q. I believe we were talking about Exhibits 5 22 and/or 6. 23 A. Oh, I'm sorry. I thought you said the chart. 24 This chart. Okay. 25 I mistake the medical record as the chart.</p>	<p style="text-align: right;">Page 89</p> <p>1 are things that I've heard of in theory but never in 2 practice. So I would -- I was kind of surprised by 3 the question. 4 That was a knee jerk. I was thinking on my 5 feet. 6 Q. I'm sorry, Doctor. Do you need a break or 7 anything? 8 A. No. No. 9 Q. Okay. 10 Now, I apologize. I was working off a 11 different chart than what Counsel has, so I don't have 12 the specific Bates number for you. But what I've got 13 is the informed consent document that you had at 14 St. Mary's Good Samaritan. And it's signed and dated 15 6/03/03. It's signed by my client Marabeth Clark, and 16 what looks to be a fellow physician or coworker Kathy 17 Dun- -- I can't read the last name. Kathy Dunbar or 18 something like that. I assume you don't recall who 19 that would be. 20 Regardless, it is the informed consent 21 document entitled, "Special Consent to Operation or 22 Other Procedure." This is at Saint Mary's Good 23 Samaritan in June of 2003. Is that understood? 24 A. I understand what you're saying, yes. 25 Q. Okay.</p>

<p style="text-align: right;">Page 90</p> <p>1 And I'm assuming it's somewhere in the 2 medical record that you've been given in Exhibit 7; 3 however, I just don't have the specific page number. 4 I'm sorry about that. 5 MS. YOUNG: Counsel, I may -- Exhibit 7 was 6 just the clinic records, and so I think on Bates label 7 number 31 there is an operative consent. But it -- I 8 don't think it's the facility consent form that you're 9 referring to. 10 I can probably find that so he has it in 11 front of him, if you want. 12 MR. GROVES: Is it within Exhibit 7? 13 MS. YOUNG: I don't think so. I just see -- 14 I see maybe a clinic consent in Exhibit 7. But -- 15 THE WITNESS: Okay. So this -- if the 16 operative consent from is it 6/16/03? 17 MR. GROVES: Q. This is actually dated 6/3 18 of '03. 19 And I'd be happy to read to you, you know, 20 the specific portion of it that I want. I should have 21 sent it to our court reporter to have for you so you 22 could look at it. But... 23 MS. YOUNG: Actually, I found it, Counsel, if 24 you'd like me to hand it to him. 25 MR. GROVES: I appreciate that. Thank you.</p>	<p style="text-align: right;">Page 92</p> <p>1 Dr. Stanford." 2 And I believe you testified that that would 3 be pretty common, you would discuss the procedure with 4 a patient beforehand; is that right? 5 A. Yes. 6 Q. And then it says, "I completely understand 7 the nature of my condition, the nature of the 8 operation or procedure to be performed, and the degree 9 of risks and benefits associated with such." 10 So I'll stop right there. So is the degree 11 of the risks associated with a particular procedure 12 something that you would discuss with your patient 13 prior to implant? 14 A. Yes. 15 Q. And then it says, "Including any possible 16 serious complications of the procedure." 17 A. Correct. 18 Q. Says, "I also have been informed of any 19 alternative treatment and the risks of benefits of 20 such by my physician." 21 Doctor, my question to you is, A, did I read 22 that properly? 23 A. Yes. 24 Q. And, B, what would be some of the alternative 25 treatment that you would give to Ms. Clark in this</p>
<p style="text-align: right;">Page 91</p> <p>1 Can you tell me what the Bates number is for 2 the record? 3 MS. YOUNG: It looks like 4 CLARKM_SMGSA_MDR00143. 5 MR. GROVES: Oh, okay. So we did have the 6 same record. I'm not quite -- 7 MS. YOUNG: Well, I had separated them 8 between clinic records and facility records. And in 9 the last few minutes that I have I'm also going to 10 introduce those as an exhibit, but I didn't have a 11 specific question about them yet. 12 MR. GROVES: Okay. Thank you, Counsel. 13 MS. YOUNG: Sure. 14 MR. GROVES: Q. Doctor, if you want to 15 familiarize yourself with that, that record, please 16 feel free. 17 A. No. Please go ahead. 18 Q. Okay. 19 I wanted to ask you about paragraph two. For 20 starters here, I'm assuming is any of that on there 21 your handwriting? I'm assuming it's not. 22 A. None of it. 23 Q. Okay. 24 Paragraph two says, "The procedures listed in 25 paragraph one have been explained to me by</p>	<p style="text-align: right;">Page 93</p> <p>1 particular situation? 2 Excuse me. That was a poorly worded 3 question. 4 What would be some of the alternative 5 treatment ideas and procedures that you would discuss 6 with Ms. Clark prior to her implant procedure? 7 A. Well, I assume you're not asking me to 8 specifically recall what I discussed with her. 9 Q. Well, no. I'm sorry. 10 A. Okay. 11 Q. In 2003 what would be some of the 12 alternatives to mesh implant that you would discuss 13 with a patient like Ms. Clark who's got complaints of 14 stress urinary incontinence? 15 A. There would have been discussions about doing 16 nothing. There were some less effective procedures 17 like a needle suspension or a radiofrequency bladder 18 neck suspension or a Burch procedure. 19 Since I was doing a laparoscopic procedure, a 20 laparoscopic Burch would have been a possibility. I 21 may or may not have mentioned them to her. And then, 22 of course, the mesh sling procedure would have been 23 discussed. 24 Q. Doctor, these alternative procedures, am I 25 correct, that you wrote a -- you were an author on an</p>



<p style="text-align: right;">Page 94</p> <p>1 article in the International Urogynecological Journal  2 that I believe was published in 2004 regarding Burch  3 urethropepy? Did I say that properly?  4 A. With Willy Davila, yes.  5 Q. I guess I don't see that name listed here. I  6 see a Laura R. Lynn, a Gordon C. Dunn, D-u-n-n?  7 A. Oh. Okay. Yeah, I'd forgotten about that  8 paper.  9 Q. And a T. Flemming Mattox?  10 A. Okay.  11 Q. Does that at all sound familiar to you at  12 all?  13 A. Yes. I'm one of the authors, I believe,  14 yes.  15 Q. And, again, this is in the International or  16 maybe it's Internal Urogynecological Journal. It's  17 published on-line date is January 9, 2004.  18 In it the conclusion is made, "We conclude  19 that the standard Burch procedure and paravaginal  20 repair can be accomplished safely and with excellent  21 short-term efficacy through a 1.50 to 2.5 inch  22 incision."  23 Does that sound familiar to you at all?  24 A. Yes.  25 MS. YOUNG: Counsel, can I interrupt just</p>	<p style="text-align: right;">Page 96</p> <p>1 both put our positions on the record.  2 MR. GROVES: I don't think that's what the  3 PTO requires. The PTO talks about documents produced.  4 And it doesn't say anything about having to disclosure  5 to you all documents that are public. It's a public  6 document.  7 MS. YOUNG: I think we both --  8 MR. GROVES: Is your objection I can't ask  9 the doctor about public documents?  10 MS. YOUNG: I think we both stated our  11 objections, and I'm not instructing -- I have no  12 authority to instruct the witness not to answer since  13 we both stated our positions. I think we should move  14 on now.  15 MR. GROVES: I was just trying to get a  16 clarification of your position.  17 MS. YOUNG: And I feel it's clear. Please go  18 ahead.  19 MR. GROVES: Okay. Thank you, Counsel.  20 Q. So, Doctor, sorry about the interruption  21 there.  22 The authors say, we quote, "We conclude that  23 the standard Burch procedure and paravaginal repair  24 can be accomplished safely and with excellent  25 short-term efficacy through a 1.5 to 2.5 inch</p>
<p style="text-align: right;">Page 95</p> <p>1 with a question?  2 MR. GROVES: Sure.  3 MS. YOUNG: Is this a document that was part  4 of the defense's document production, or is this  5 something else?  6 MR. GROVES: I couldn't tell you whether it  7 was or whether it wasn't. It's a published journal.  8 MS. YOUNG: Okay.  9 To the extent it was part of the defense  10 document production, I just need to object for the  11 record for failure to provide notice as required by  12 the PTOs.  13 Go ahead.  14 MR. GROVES: Well, I guess I'll just state  15 for the record that I didn't know that the PTOs  16 eviscerates documents which are in the public sphere  17 just because you did or did not produce them. And, of  18 course, we don't know if you did produce this.  19 MS. YOUNG: Well, there are millions of  20 documents I believe that were produced.  21 MR. GROVES: You're right.  22 MS. YOUNG: But because you are using it, I  23 would say it would be your responsibility to know  24 whether or not it was covered by the PTO. But I don't  25 want to get into an argument about it. I think we</p>	<p style="text-align: right;">Page 97</p> <p>1 incision."  2 Does that sound familiar to you at all?  3 A. Yes.  4 Q. Okay.  5 And I'll read the entire title of the paper.  6 "Is mini-incisional Burch urethropepy a less  7 invasive method to accomplish a time tested procedure  8 for treatment of genuine stress incontinence."  9 And, Doctor, so we're clear. Would the Burch  10 procedure have been something that in 2003 would have  11 been available as an alternative procedure to  12 Mrs. Clark?  13 A. Yes. I think I stated that earlier.  14 Q. Okay.  15 And I'm sorry if I -- I'm sorry if I'm making  16 you retread a little bit, Doctor.  17 A. It's okay.  18 Q. I guess what I would like to do real quick is  19 mark Exhibit 8. The court reporter should have it.  20 (Whereupon Defendant's  21 Exhibit 8 was marked for  22 identification.)  23 MR. GROVES: Q. Doctor, have you ever seen  24 this document before?  25 A. Probably, but I can't specifically recall</p>



<p style="text-align: right;">Page 98</p> <p>1 where or when.  2 Q. That's okay.  3 And I'll just note for the record there, I  4 believe it's dated 2000.  5 A. Okay.  6 Q. If you'll skip down to kind of the bottom  7 portion of it there. It says -- there's a section on  8 adverse reactions. Or adverse events. Excuse me.  9 Adverse reactions.  10 A. Where?  11 Q. I believe it's on page ETH.MESH and then a  12 long number ending in 383.  13 A. This would be on page 28?  14 Q. Yeah. I'm sorry, yes. We'll ignore -- I  15 think that it's Russian over there on the right-hand  16 side. Page 28.  17 A. All right.  18 Q. And bullet number three it says, in the  19 adverse reaction section, it says that mesh may  20 potentiate an existing infection.  21 Is that information you would pass along to  22 your client, to your own patients?  23 A. I'm sorry. I don't see what he's talking  24 about.  25 Q. Oh, I'm sorry. Bullet number three. It</p>	<p style="text-align: right;">Page 100</p> <p>1 correct answer.  2 Okay. So no, I don't read that it states  3 that it could potentiate a new infection. I don't  4 read that.  5 MR. GROVES: Q. Okay.  6 Doctor, bullet one discusses punctures or  7 lacerations which may require repair. Would you agree  8 with me that that bullet is referenced an adverse  9 reaction regarding surgical technique or surgical  10 placement of the sling, not a complication of the  11 sling itself?  12 A. I don't know how to separate those two.  13 Q. Well, it references, "During needle passage  14 and may require surgical repair."  15 My question to you is, is needle passage, is  16 that a complication or an adverse reaction to the  17 sling itself, or do you read that as a reference to  18 surgical technique?  19 MS. YOUNG: Object to form. Asked and  20 answered.  21 THE WITNESS: Yeah, again, I really don't  22 know how to separate the two.  23 MR. GROVES: Q. Doctor, looking at these  24 IFUs, would you agree that these -- that this IFU  25 does not warn that the mesh may cause chronic</p>
<p style="text-align: right;">Page 99</p> <p>1 starts with, "As with all foreign bodies."  2 A. Oh, okay.  3 Well, yeah, but -- yeah. I would -- no, I  4 would not discuss this specifically with a patient.  5 But that's how -- that's how it elicits a reaction to  6 hold the mesh in place. So that's -- that's the  7 normal physiologic reaction of implanting the wide  8 pore monofilament polypropylene mesh.  9 Q. Okay.  10 A. I would not have discussed this with a  11 patient unless they specifically asked.  12 Q. Would you agree with me that an existing  13 infection is an infection that is already present in  14 the patient before the TVT is implanted?  15 A. Yes. I mean, it doesn't say preexisting.  16 But, yes.  17 So I assume existing here means something  18 that is currently present at the time.  19 Q. Okay. Thank you, Doctor.  20 Doctor, in this IFU adverse reactions section  21 would you agree we me that the labeling in this TVT  22 IFU does not indicate that the mesh may potentiate a  23 new infection in the patient?  24 MS. YOUNG: Object to form.  25 THE WITNESS: I'm reading so I can give you a</p>	<p style="text-align: right;">Page 101</p> <p>1 inflammation?  2 A. No, it does. Page 28, second bullet point.  3 It could result in extrusion, erosion, fistula  4 formation and inflammation.  5 Q. My question to you was do you agree that this  6 IFU does not warrant that the mesh could cause, quote,  7 "chronic inflammation"?  8 MS. YOUNG: Object to form.  9 THE WITNESS: I don't know. Again, I don't  10 want to be argumentative, but the question is  11 nonsensical. I don't see the word chronic  12 inflammation.  13 MR. GROVES: Q. Okay.  14 Would you agree that that IFU does not warn  15 that the mesh may cause chronic vaginal pain?  16 A. I'll agree with you it does not say the word  17 chronic.  18 Q. Would you agree that that IFU does not warn  19 the mesh may cause permanent painful intercourse?  20 A. Yes, I'll agree that it does not say that.  21 Q. Would you agree that it does not warn that  22 this product could cause painful intercourse?  23 A. I don't -- I do not see that written here,  24 no.  25 Q. Would you agree that this IFU does not warn</p>

<p style="text-align: right;">Page 102</p> <p>1 that this mesh product may cause chronic urinary tract</p> <p>2 infection?</p> <p>3 A. I agree it does not say that.</p> <p>4 Q. Would you agree that -- that doesn't answer</p> <p>5 my question.</p> <p>6 Would you agree the IFU does not warn that</p> <p>7 the product may cause chronic urinary tract infection?</p> <p>8 MS. YOUNG: Object to the form of the</p> <p>9 question.</p> <p>10 THE WITNESS: And I've agreed with you. Yes.</p> <p>11 MR. GROVES: Q. Are these the type of</p> <p>12 things that you would want the mesh manufacturer to</p> <p>13 make the prescribing implanting physician aware of</p> <p>14 prior to implant procedure?</p> <p>15 A. No, not necessarily.</p> <p>16 MS. YOUNG: Object to form.</p> <p>17 MR. GROVES: Q. I don't understand your</p> <p>18 answer.</p> <p>19 Not necessarily. Does that mean sometimes</p> <p>20 yes, sometimes no, or --</p> <p>21 A. No. I think I've answered this to you</p> <p>22 before. I -- first of all, I would not rely on this</p> <p>23 for any purpose at all. This is something that's</p> <p>24 required by the government. So whether it</p> <p>25 specifically states something or not, I would not rely</p>	<p style="text-align: right;">Page 104</p> <p>1 painful intercourse, chronic urinary tract infection.</p> <p>2 And I asked you are these the type of things you'd</p> <p>3 want to be made aware of as an implanting physician by</p> <p>4 the manufacturer?</p> <p>5 A. I think I'll use the same answer I used</p> <p>6 before.</p> <p>7 I wouldn't necessarily rely on the</p> <p>8 manufacturer to tell me that information. I probably</p> <p>9 would rely on other scholarly activities that point</p> <p>10 out the complications of these procedures. And --</p> <p>11 Q. Okay. Fair enough.</p> <p>12 I'll ask a similar version of the same</p> <p>13 question.</p> <p>14 Are these the types of things that you would</p> <p>15 want to be made aware of as the implanting physician</p> <p>16 prior to your implant?</p> <p>17 A. Yes.</p> <p>18 Q. Thank you.</p> <p>19 A. But I think I said yes a few times. Sorry.</p> <p>20 But I thought I did.</p> <p>21 Q. Doctor, you'd agree with me that these IFUs</p> <p>22 do not warn that mesh may defray, do they?</p> <p>23 A. I don't see that written on this, no.</p> <p>24 Q. If the manufacturer knows in 2003, prior to</p> <p>25 the time of your implant of Ms. Clark, that its product</p>
<p style="text-align: right;">Page 103</p> <p>1 on this.</p> <p>2 And I don't know how the manufacturer could</p> <p>3 put in all of the nuanced words that would be</p> <p>4 required. So I -- I guess I'm a little, still a</p> <p>5 little stumped by the direction of the questions</p> <p>6 because I'm agreeing that, yes, it doesn't say some of</p> <p>7 the things you've asked. But, again, I would never</p> <p>8 rely to this piece of paper for anything.</p> <p>9 Q. Well, I'm going to strike your answer and</p> <p>10 have the court reporter reread my question.</p> <p>11 A. Okay.</p> <p>12 MS. YOUNG: You can move to strike. But go</p> <p>13 ahead.</p> <p>14 MR. GROVES: Sorry. I'll move to strike.</p> <p>15 And I ask the court reporter to please read</p> <p>16 my question again.</p> <p>17 Thank you.</p> <p>18 (Record read.)</p> <p>19 MR. GROVES: Q. I'll go ahead and reread</p> <p>20 it.</p> <p>21 If Counsel objects asked and answered, then</p> <p>22 I'm going to have the court reporter reread it. And</p> <p>23 I'll just put that out there.</p> <p>24 So the question was, Doctor, we talked about</p> <p>25 chronic inflammation, chronic vaginal pain, permanent</p>	<p style="text-align: right;">Page 105</p> <p>1 may degrade in the human body, is that information</p> <p>2 that you would want to be made aware of prior to</p> <p>3 implant?</p> <p>4 MS. YOUNG: Object to form.</p> <p>5 THE WITNESS: Yes.</p> <p>6 MR. GROVES: Q. Doctor, you'd agree that</p> <p>7 these IFUs do not warn that the mesh may fray, rope</p> <p>8 or curl when implanted in the human body, correct?</p> <p>9 A. I do not see it written here, so correct.</p> <p>10 Q. Doctor, prior to your implant of Ms. Clark in</p> <p>11 2003 if the manufacturer knew that its product may</p> <p>12 fray, rope or curl, is that information that you would</p> <p>13 like to be made aware of?</p> <p>14 MS. YOUNG: Object to form.</p> <p>15 (Court reporter asks for</p> <p>16 clarification.)</p> <p>17 MS. YOUNG: Counsel, did you say fray, rope</p> <p>18 or curl?</p> <p>19 MR. GROVES: Yes, I did. Thank you.</p> <p>20 COURT REPORTER: Rope, r-o-p-e?</p> <p>21 THE WITNESS: Roll.</p> <p>22 COURT REPORTER: Roll, r-o-l-l?</p> <p>23 THE WITNESS: Rope or roll?</p> <p>24 MR. GROVES: Rope.</p> <p>25 A. Rope.</p>

<p style="text-align: right;">Page 106</p> <p>1 Yes, I guess I would like to know that. Yes.</p> <p>2 Q. Doctor, these things that we've been</p> <p>3 discussing, the chronicity, the permanency, things of</p> <p>4 that nature, are those the types of things that you</p> <p>5 would want to pass on to your patients prior to</p> <p>6 implant?</p> <p>7 A. Maybe not that specifically. But, yes, there</p> <p>8 would be -- there would be probably a more generic</p> <p>9 discussion about the complications. But probably not</p> <p>10 as specific as you're asking, no.</p> <p>11 Q. So going back to your informed consent where</p> <p>12 it says you discussed the degree of these sorts of</p> <p>13 things --</p> <p>14 A. Um-hum.</p> <p>15 Q. -- that's the type of information you want to</p> <p>16 know and pass along to your patients prior to implant,</p> <p>17 correct?</p> <p>18 A. Well, that's not my consent. That's the</p> <p>19 hospital's consent about the degree.</p> <p>20 Q. So you're saying you would not discuss the</p> <p>21 degree of these things with your patient prior to</p> <p>22 implant?</p> <p>23 MS. YOUNG: Object to form.</p> <p>24 THE WITNESS: What do you mean by degree?</p> <p>25 You mean prevalence, or the chance of them happening?</p>	<p style="text-align: right;">Page 108</p> <p>1 Q. Doctor, would you agree with me that the IFU</p> <p>2 contains no procedure describing the proper procedure</p> <p>3 for removal of the mesh product?</p> <p>4 A. I don't see that here, no.</p> <p>5 Q. Would you agree with me that the IFU contains</p> <p>6 no indication for removal of the mesh product?</p> <p>7 A. I agree with you.</p> <p>8 Q. Would you agree with me this IFU contains no</p> <p>9 adverse reactions associated with removal of the mesh</p> <p>10 product?</p> <p>11 A. No, it doesn't state that, no.</p> <p>12 Q. As a physician who is performing implanting</p> <p>13 and removal of these products, wouldn't you want to</p> <p>14 know Ethicon's method of procedure for removal of its</p> <p>15 mesh product?</p> <p>16 A. No.</p> <p>17 Q. As a physician who is implanting and doing</p> <p>18 removal procedures, if Ethicon knew of adverse events</p> <p>19 associated with removal of its product, wouldn't you</p> <p>20 want to know what those events are, if any?</p> <p>21 MS. YOUNG: Object to form. Lack of</p> <p>22 foundation.</p> <p>23 THE WITNESS: Could you please repeat that?</p> <p>24 MR. GROVES: Q. As an implanting physician</p> <p>25 who may also do removal, if Ethicon knew of adverse</p>
<p style="text-align: right;">Page 107</p> <p>1 Is that what you mean?</p> <p>2 MR. GROVES: I mean degree of risks.</p> <p>3 MS. YOUNG: Object to form.</p> <p>4 THE WITNESS: Okay. No, I would discuss to</p> <p>5 some extent the degree of certain risks. Yes, I</p> <p>6 would.</p> <p>7 MR. GROVES: Q. Doctor, you'd agree with me</p> <p>8 this IFU describes procedures for implanting the</p> <p>9 device, correct?</p> <p>10 A. Oh, I don't know. Does it?</p> <p>11 No, I don't think it does.</p> <p>12 Oh, wait. I'm sorry. Instructions for use.</p> <p>13 Page 26?</p> <p>14 Q. I'm sorry. I'm talking about the document,</p> <p>15 the exhibit in general, the instructions for use.</p> <p>16 Yeah, do they describe procedure for implanting this</p> <p>17 product?</p> <p>18 A. Yeah, it says instructions for use. So, yes,</p> <p>19 I guess it does. Um-hum.</p> <p>20 Q. Okay.</p> <p>21 And, Doctor, please feel free to look over it</p> <p>22 if you want.</p> <p>23 Does it also describe indications for use of</p> <p>24 this product?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 109</p> <p>1 events associated with removal of its product,</p> <p>2 wouldn't you want to know those events, what they are,</p> <p>3 if any?</p> <p>4 MS. YOUNG: Same objection.</p> <p>5 THE WITNESS: No. I think, again, I wouldn't</p> <p>6 rely on Ethicon for that information.</p> <p>7 I would get that probably from scholarly</p> <p>8 journals or other educational materials. And in this</p> <p>9 case, of course, it wasn't removed. It was lysed.</p> <p>10 MR. GROVES: Q. Doctor, in March or April</p> <p>11 of 2008 -- and maybe tell me if this is one of the</p> <p>12 journals that you've done more work on. The Journal</p> <p>13 of Minimally Invasive Gynecology has a published</p> <p>14 article where you are I believe the lead author</p> <p>15 entitled, "Comprehensive Review of Suburethral Sling</p> <p>16 procedure complication." Does that sound familiar to</p> <p>17 you at all?</p> <p>18 A. Yes.</p> <p>19 Q. Okay.</p> <p>20 You and an author named Marie Padilla R.</p> <p>21 Paraiso.</p> <p>22 A. Paraiso. From Cleveland Clinic, yes.</p> <p>23 Q. In it you did some, I guess, statistical</p> <p>24 analysis. Is that fair to call it?</p> <p>25 A. No. I -- well, I guess you could call it</p>

<p style="text-align: right;">Page 110</p> <p>1 that, yes.</p> <p>2 Q. In my understanding in just kind of looking</p> <p>3 through the beginning section here where you are</p> <p>4 discussing, I guess, some of your research procedures,</p> <p>5 you talked about doing PubMed research and also using</p> <p>6 the Manufacturer and User Facility Device Experience</p> <p>7 database. Does that sound familiar to you at all?</p> <p>8 A. That was the methods we used to get the</p> <p>9 information, yes. The MAUDE database and PubMed.</p> <p>10 Q. I'm sorry. I didn't hear that. The what</p> <p>11 database?</p> <p>12 A. MAUDE.</p> <p>13 Q. Can you tell me a little bit about the MAUDE</p> <p>14 database, Doctor?</p> <p>15 A. Yes.</p> <p>16 Anytime there is an adverse event that occurs</p> <p>17 the hospital and/or manufacturer is supposed to report</p> <p>18 to the MAUDE database so that the -- I believe it's the</p> <p>19 FDA branch of the government can collect and collate</p> <p>20 information about adverse events. Of any device</p> <p>21 that's FDA approved.</p> <p>22 Q. So MAUDE is an FDA database?</p> <p>23 A. I don't know that for a fact.</p> <p>24 Q. And, Doctor, and if this is too long ago,</p> <p>25 just tell me if you don't recall.</p>	<p style="text-align: right;">Page 112</p> <p>1 MR. GROVES: Q. Doctor, in your conclusions</p> <p>2 of this article we've been discussing in 2008 authored</p> <p>3 by -- authored by you in the Minimally Invasive</p> <p>4 Gynecology Journal, the conclusion states that</p> <p>5 sling-related complications are vastly unreported and</p> <p>6 studies with long term follow-up are lacking.</p> <p>7 Does that sound correct?</p> <p>8 A. Is that what I wrote?</p> <p>9 Q. Yes, sir.</p> <p>10 A. Well, at that point in time it was probably</p> <p>11 correct.</p> <p>12 Q. You state, "Mesh-related complications are</p> <p>13 less when macroporous, loosely knitted polypropylene</p> <p>14 mesh is used."</p> <p>15 Does that sound correct, Doctor?</p> <p>16 A. That is correct.</p> <p>17 Q. Doctor, do you have an understanding of the</p> <p>18 TVT Gynecare mesh that was implanted in Ms. Clark?</p> <p>19 A. I do.</p> <p>20 Q. Is it a loosely knitted polypropylene mesh?</p> <p>21 A. It is.</p> <p>22 Q. Okay.</p> <p>23 A. Monofilament. Yes.</p> <p>24 Q. Doctor, if a mesh manufacturer were to</p> <p>25 undertake a long-term follow-up study, is that</p>
<p style="text-align: right;">Page 111</p> <p>1 In compiling your research and ultimately</p> <p>2 coming to your conclusions for this particular</p> <p>3 article, isn't it true that you predominantly relied</p> <p>4 upon your own research and PubMed as opposed to MAUDE?</p> <p>5 A. Yes, I do think that the MAUDE database did not</p> <p>6 provide as much information as published research.</p> <p>7 Q. And, Doctor, if I said that you -- you noted</p> <p>8 as the lead author in this you consider that MAUDE</p> <p>9 proved to be of limited use, you wouldn't disagree</p> <p>10 with me; isn't that correct?</p> <p>11 A. Yeah, I think that's probably true.</p> <p>12 I need to text my office real quick.</p> <p>13 MR. GROVES: If we need to go off the record,</p> <p>14 please.</p> <p>15 THE WITNESS: I just need to postpone a</p> <p>16 meeting.</p> <p>17 MR. GROVES: I'm sorry, Doctor. I only have</p> <p>18 about ten minutes left, and I will try to wrap up here</p> <p>19 sooner than that.</p> <p>20 MS. YOUNG: We'll go off for just a second.</p> <p>21 VIDEOGRAPHER: We are going off the record at</p> <p>22 2:02 p.m.</p> <p>23 (Recess taken.)</p> <p>24 VIDEOGRAPHER: All right. We are back on the</p> <p>25 record at 2:05 p.m.</p>	<p style="text-align: right;">Page 113</p> <p>1 information that you would consider as a physician?</p> <p>2 A. Sure. Yes.</p> <p>3 Q. Thank you, Doctor.</p> <p>4 Let me look over my notes. I'll reserve the</p> <p>5 rest of my time.</p> <p>6</p> <p>7 REEXAMINATION</p> <p>8</p> <p>9 BY MS. YOUNG:</p> <p>10 Q. Okay, Doctor. I'm going to ask you, if you</p> <p>11 would, to look at Exhibit 7 again.</p> <p>12 Do these appear to be the clinic records for</p> <p>13 Ms. Marabeth Clark?</p> <p>14 A. Yes.</p> <p>15 Q. And would these have been kept in the normal</p> <p>16 course of the business of this medical practice and</p> <p>17 clinic?</p> <p>18 A. Yes.</p> <p>19 Q. Would they have been created near or at the</p> <p>20 time that the treatment was given?</p> <p>21 A. Yes.</p> <p>22 Q. Also I want to hand you what I'll marked as</p> <p>23 Exhibit -- are we on 9? Okay. Exhibit 9.</p> <p>24 /////</p> <p>25</p>

<p style="text-align: right;">Page 114</p> <p>1 (Whereupon Defendant's 2 Exhibit 9 was marked for 3 identification.) 4 MS. YOUNG: Q. And, Counsel, I'm handing 5 him the records we have off Marker from St. Mary's 6 Good Samaritan. They start with SMGSA_MDR00083. 7 Doctor, do these appear to be the facility 8 records for Ms. Marabeth Clark? 9 A. Yes. 10 Q. Beginning with June 30th, '03, the date of 11 her implant procedure? 12 A. Yes. 13 Q. And would these have been kept in the regular 14 course of business? 15 A. Yes. 16 Q. Would they have been made at or near the time 17 of Ms. Clark's treatment? 18 A. Yes. 19 Q. And you were kind enough to say that even 20 though you hadn't brought a CV, that you would be 21 willing to e-mail a copy of that to our court reporter 22 today; is that right? 23 A. Yes. 24 Q. Okay. 25 I'd like to make that Exhibit 10 to be mailed</p>	<p style="text-align: right;">Page 116</p> <p>1 A. Oh, yes. 2 Q. In your clinical experience that you've 3 outlined for us today, what kind of impact have you 4 observed it to have? 5 A. Well, as you can see in the questionnaire, 6 the patient gets to judge how impactful on their 7 quality of life it is. And in some cases some women 8 it's -- it doesn't bother them much at all. 9 In others, it impacts them to the point where 10 they become reclusive, stop exercising. It can damage 11 relationships. It can create work place problems. It 12 can create depression. And it can really alter the 13 patient's quality of life. And, you know, everybody's 14 different in how it impacts them. 15 Q. And in the questionnaire from your clinic 16 that we reviewed that Ms. Clark had filled out, did 17 she indicate that it was bothering her enough that she 18 wanted a surgical treatment for it? 19 A. Yes. 20 Q. And when she decided to have that surgical 21 treatment, that wasn't the first time she had come to 22 you with problems with incontinence was it? 23 A. No. In fact, we followed her for over a year 24 until she got to the point where she wanted something 25 more definitive done, so we did more testing,</p>
<p style="text-align: right;">Page 115</p> <p>1 to us once our court reporter has received that. 2 Doctor, would you please look at Exhibit 6, 3 the list of the chart that has potential risks of 4 non-mesh and mesh SUI surgeries on it? 5 A. Yes. 6 Q. I believe you testified earlier that all of 7 the risks listed under the mesh column on the right 8 were risks that you would have been aware of as being 9 associated with mesh SUI surgeries at the time of 10 Ms. Clark's procedure; is that correct? 11 A. Yes. 12 Q. And at that time would you have been aware 13 that any of these risks could have been temporary or 14 chronic? 15 A. Yes. 16 Q. And at that time would you have been aware 17 that any of these risks could have been mild, 18 moderate, or severe? 19 A. Yes. 20 Q. And specifically do these lists include pain 21 with intercourse, vaginal scarring, urinary retention, 22 and one or more surgeries to treat an adverse event? 23 A. Yes. 24 Q. Doctor, can stress urinary incontinence have 25 an impact on a woman's life?</p>	<p style="text-align: right;">Page 117</p> <p>1 confirmed the diagnosis and moved on with the 2 procedure. 3 Q. I want to ask you some questions about the 4 device itself and some allegations in the lawsuit. 5 Doctor, there's a claim made in this case 6 that TVT mesh is cytotoxic. Can we agree that 7 cytotoxic means cell death? 8 A. Yeah. Yes. 9 Q. After implanting Ms. Clark with the TVT, did 10 you find any evidence that she had been harmed by the 11 mesh allegedly being cytotoxic? 12 MR. GROVES: Object to form. 13 THE WITNESS: First of all, I don't know how 14 I would know that it's cytotoxic. But, no, I don't 15 believe the mesh itself is cytotoxic. 16 MS. YOUNG: Q. Is that something that 17 you've seen in any of your patients where you have 18 either implanted a TVT or done a subsequent procedure 19 involving a TVT? 20 A. Not -- 21 MR. GROVES: Object to form. Lacks 22 foundation. 23 THE WITNESS: Okay. I'm not sure what lack 24 of foundation means. 25 But, no, I've never, with a monofilament</p>



<p style="text-align: right;">Page 118</p> <p>1 macroporous mesh like this, no, I've never seen that.</p> <p>2 MS. YOUNG: Q. There's also a claim in the</p> <p>3 lawsuit that the TVT device degrades and falls apart</p> <p>4 or leaches chemicals into the body.</p> <p>5 In the time that you treated Ms. Clark after</p> <p>6 the implant, did you see any evidence of the TVT</p> <p>7 device degrading, falling apart or leaching chemicals</p> <p>8 into her body?</p> <p>9 A. Not at all.</p> <p>10 Q. Have you seen in any of your patients</p> <p>11 evidence of a TVT device degrading, falling apart or</p> <p>12 leaching chemicals into the body?</p> <p>13 A. Not at all.</p> <p>14 Q. There's also a claim in this case that the</p> <p>15 TVT mesh frays and sheds particles both before and</p> <p>16 after it's implanted. Have you ever seen such</p> <p>17 evidence in any of your patients that a TVT device has</p> <p>18 frayed or shed particles?</p> <p>19 MR. GROVES: Object to form. Calls for</p> <p>20 general cause expert testimony. I don't believe</p> <p>21 Counsel has retained the witness to call such</p> <p>22 testimony.</p> <p>23 THE WITNESS: No, I've never seen anything</p> <p>24 that makes me think that that occurs.</p> <p>25 MS. YOUNG: Q. Before you implanted the TVT</p>	<p style="text-align: right;">Page 120</p> <p>1 macrophages would infiltrate the mesh.</p> <p>2 They would lay down a collagen material which</p> <p>3 is, of course, a part of a scar. And in doing so it</p> <p>4 would tend to contract locally, and so the mesh would</p> <p>5 be encompassed locally into a scar.</p> <p>6 And this occurs over about a -- it begins</p> <p>7 occurring over about a two-week period and finalizes</p> <p>8 over about a year.</p> <p>9 So that's the normal mechanism. So, yes, you</p> <p>10 would expect for the body to incorporate the mesh in</p> <p>11 totality.</p> <p>12 Q. Does the TVT sling treat urge incontinence to</p> <p>13 your understanding?</p> <p>14 A. Actually, there is some research showing that</p> <p>15 it could. It wouldn't be the primary indication. But</p> <p>16 it could. It could in some women correct urge</p> <p>17 symptoms.</p> <p>18 MR. GROVES: I think we're going beyond the</p> <p>19 scope of your direct or any questions I asked,</p> <p>20 Counsel.</p> <p>21 MS. YOUNG: I reserved additional time to</p> <p>22 complete my questioning. It's not redirect.</p> <p>23 Q. Doctor, why did you recommend the TVT to</p> <p>24 Ms. Clark as opposed to the Burch procedure?</p> <p>25 A. I don't recall. At this stage I don't</p>
<p style="text-align: right;">Page 119</p> <p>1 in Ms. Clark, did you notice any particle loss or bits</p> <p>2 of mesh breaking off of the TVT?</p> <p>3 A. No.</p> <p>4 Q. If you had seen that, what would you have</p> <p>5 done?</p> <p>6 A. I'm not sure.</p> <p>7 Q. Have you ever encountered that?</p> <p>8 A. No.</p> <p>9 Q. After implanting mesh or after implanting the</p> <p>10 mesh in Ms. Clark, did you find any evidence that the</p> <p>11 mesh had roped or curled in her?</p> <p>12 A. No.</p> <p>13 Q. Did you find any evidence with Ms. Clark that</p> <p>14 the mesh had shrunk or contracted?</p> <p>15 A. No. But it is supposed to shrink a small</p> <p>16 percentage. It's just part of the natural healing</p> <p>17 process that causes the mesh to shrink. So I can't</p> <p>18 specifically say I saw it, but it is something I would</p> <p>19 expect.</p> <p>20 Q. And explain, if you would for the jury, why</p> <p>21 that's an expected and necessary part of the healing</p> <p>22 process?</p> <p>23 A. So when the mesh is placed into the tissue</p> <p>24 and then, of course, it's now encompassed in the</p> <p>25 tissue, the expectation is that specific cells such as</p>	<p style="text-align: right;">Page 121</p> <p>1 recall.</p> <p>2 Q. In general what sort of things do you</p> <p>3 consider when deciding whether to recommend a TVT</p> <p>4 sling as opposed to another surgical option?</p> <p>5 MR. GROVES: Object to form.</p> <p>6 THE WITNESS: I think as we discussed</p> <p>7 earlier, there was a shift away from more invasive</p> <p>8 procedures like the Burch. And so the options would</p> <p>9 have been discussed. During the informed consent the</p> <p>10 decision to combine TVT with the LAVH would have been</p> <p>11 sort of what we resolved from the discussion.</p> <p>12 I do know that at that point I was still</p> <p>13 doing Burches, so I'm pretty sure it was part of the</p> <p>14 discussion.</p> <p>15 MS. YOUNG: Q. And without remembering her</p> <p>16 specifically, can you tell from the medical records</p> <p>17 whether you decided her best option would be a TVT?</p> <p>18 MR. GROVES: Objection. Asked and</p> <p>19 answered.</p> <p>20 THE WITNESS: Well, no, it actually wasn't</p> <p>21 answered because we didn't -- there was one section in</p> <p>22 the medical record where there's a diagram that</p> <p>23 reflects what's called the POP-Q. And If you look at</p> <p>24 the numbers, she did not have anterior compartment</p> <p>25 prolapse.</p>



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1 In a patient with anterior compartment  
2 prolapse, I would probably be more inclined to do a  
3 procedure to correct the prolapse, which a Burch could  
4 have done that along with a paravaginal repair. Since  
5 she didn't have that, doing the LAVH and supporting  
6 the top of the vagina along with a sling would have  
7 actually been a very rational decision.  
8 Q. Putting yourself back in the time frame of  
9 Ms. Clark's procedure with the knowledge that you have  
10 gained since about the TVT, in your opinion is the TVT  
11 still a safe and effective treatment for stress  
12 urinary incontinence in women?  
13 A. Yes.  
14 Q. Putting yourself back in the time of  
15 Ms. Clark's procedure in 2003 but with the knowledge  
16 and information that you've gained even through today,  
17 in your opinion do the potential benefits of using the  
18 TVT to treat SUI outweigh the potential risks?  
19 A. Yes.  
20 Q. You mentioned the procedure that Ms. Clark  
21 had at the same time as her TVT implant. Was that a  
22 hysterectomy?  
23 A. Yes.  
24 Q. And can a hysterectomy result in painful  
25 intercourse?

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1 A. Yes.  
2 Q. Can a hysterectomy result in vaginal  
3 scarring?  
4 A. Yes.  
5 Q. Those are all the questions that I have,  
6 Doctor. Thank you for your time.  
7 MR. GROVES: Thank you for your time, Doctor.  
8 I'm sorry if we kept you past the meeting.  
9 THE WITNESS: We're done?  
10 MS. YOUNG: Yes.  
11 VIDEOGRAPHER: All right. We are going off  
12 the record at 2:21 p.m.  
13 (Whereupon the deposition  
14 of EDWARD STANFORD, M.D.  
15 concluded at 2:21 p.m.)  
16 (Whereupon Defendant's  
17 Exhibit 10 was marked for  
18 identification.)  
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1  
2 ACKNOWLEDGMENT OF DEPONENT  
3  
4 I, \_\_\_\_\_, do  
5 hereby certify that I have read the  
6 foregoing pages, and that the same is  
7 a correct transcription of the answers  
8 given by me to the questions therein  
9 propounded, except for the corrections or  
10 changes in form or substance, if any,  
11 noted in the attached Errata Sheet.  
12  
13  
14  
15 EDWARD STANFORD, M.D. DATE  
16  
17  
18 Subscribed and sworn  
19 to before me this  
20 \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.  
21 My commission expires: \_\_\_\_\_  
22  
23  
24  
25 Notary Public

1 STATE OF CALIFORNIA )

: ss

2 COUNTY OF STANISLAUS )

3 I, ANNETTE M. DERUYTER, do hereby certify  
4 that I am a licensed Certified Shorthand Reporter,  
5 duly qualified and certified as such by the State of  
6 California;

7 That prior to being examined, the witness  
8 named in the foregoing deposition was by me duly sworn  
9 to testify to the truth, the whole truth, and nothing  
10 but the truth;

11 That the said deposition was by me recorded  
12 stenographically at the time and place herein  
13 mentioned; and the foregoing pages constitute a full,  
14 true, complete and correct record of the testimony  
15 given by the said witness;

16 That I am a disinterested person, not being  
17 in any way interested in the outcome of said action,  
18 or connected with, nor related to any of the parties  
19 in said action, or to their respective counsel, in any  
20 manner whatsoever.

21 DATED: \_\_\_\_\_

22

23

\_\_\_\_\_  
Annette M. DeRuyter  
Calif. CSR #9816

24  
25